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ANNUAL RESEARCH PROGRESS REPORT, FISCAL YEAR 1981,(U)
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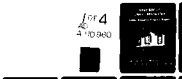

LEVEL II

(12)

DEPARTMENT OF CLINICAL INVESTIGATION

Annual Research Progress Report

FISCAL YEAR 1981

Brooke Army Medical Center
Fort Sam Houston, Texas 78234

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

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18. SUPPLEMENTARY NOTES

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Clinical Investigations, all medical specialties
Investigational protocols
Publications, Presentations (at national, international, and regional science meetings)
Detail Summary Sheets to include status and key words. (cont. on reverse side)

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Human Use Committee, and the Laboratory Animal Use Committee and registered with the Department of Clinical Investigations during Fiscal Year 1981. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were conducted under the provisions of AR 40-38, as amended, Clinical
(continued on reverse side)

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Block 19. Key Words

Southwest Oncology Group
Gynecology Oncology Group
Polycythemia Vera Study Group
Pediatric Oncology Group

Block 20. Abstract

Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; USAMRDC 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports; and BAMC Memo 40-98, Department of Clinical Investigation, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies. Research studies involving the use of laboratory animals were conducted under the provisions of AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs.

FOREWORD

"When I use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean - neither more nor less."

"The question is," said Alice, "Whether you can make words mean so many different things."

"The question is," said Humpty Dumpty, "Which is to be master - that's all." (Carroll, L. Through the Looking Glass, 1871)

Although we are confronted at times with "distinctions" (meaning "whose budget?") between clinical investigation and medical research, it is of more importance to clearly define the lack of difference between high quality patient care and active clinical investigation. Despite recognition of this concept by medical organizations and hospital accreditation groups (eg., JCAH), the general public and the bureaucracy controlling the purse strings often perceives research as unnecessary, a diversion of time from patient care, and an acceptable area from which to trim the budget. It is easy looking backwards to justify the time and money spent by clinical investigators such as Walter Reed, Roger Brooke, and William Beaumont. Their medical research produced the best patient care, not only for the subjects of their investigations, but for society as a whole. It is more difficult to look forward.

"The political ambience of our time compels the scientific community to seek firm grounds for receiving a share of public resources. It might be far more realistic, however, as well as useful, for all parties to agree that, after all, we really can't measure these things with any precision and that the most difficult segment to measure, basic research, isn't so expensive that we can't afford to run on the principle that it should be kept reasonably plump." (Greenberg, D.S. Washington report. N. Engl. J. Med. 301:1456, 1979)

It thus becomes our responsibility to become master of the words "clinical investigation" and to assure their meaning is clearly understood as being synonymous with continuous improvement in the quality of patient care. Clinicians must assume active roles in formulating policies regulating research and educating those in control of financial resources as well as the general public. Often the public's perception of benefit to the patient and society overshadows the scientific merit or medical importance of any clinical investigation. With the current emphasis on patients assuming greater responsibility for decisions regarding their health care, it is imperative that the positive contributions of medical research to improved quality of care be made clear to patients and society.

BAMC has been fortunate in having a command leadership that is outstanding in its support of clinical investigations. There has been a growth in the number of active protocols (as well as their quality), the number of publications and presentations, the Department of Clinical Investigation staff available to support research, and facilities, especially the new Laboratory Animal Research and Training Center. The real credit for the work presented in this volume belongs to the clinical investigators (from principal investigators to laboratory technicians) who have devoted their time and talents to increasing medical knowledge and quality of care. Equally important are the patient volunteers who freely consented, sometimes without direct benefit to themselves, to participate in gathering new knowledge and providing a base for improved patient care.

UNIT SUMMARY - FISCAL YEAR 1981

A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.

2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.

3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.

4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.

5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.

6. To maintain a high professional standard and accreditation of advanced health programs.

7. To assure the highest level of professional standards in the conduct of human research.

B. Technical Approach

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-18 and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

C. Staffing

Name	Rank	MOS	Title
Anderson, James H., Jr.	MAJ	61C00	Chief, Endocrinologist
Burleson, David G.	MAJ	68C00	Laboratory Director/Biochemist
Lieberman, Michael M.	CPT	68A00	Microbiologist
Madonna, Gary S.	CPT	68A00	Microbiologist
Merrill, Gerald A.	CPT	68A00	Microbiologist
Quagliani, Joseph G.	1LT	68J00	Biomedical Information Off.
Loyd, Charles M.	SFC	92B3R	Sr Med Lab Sp, NCOIC
Sinegal, John H.	SSG	92B2R	Med Lab Sp
Diaz, Noel	SP5	92B2R	Med Lab Sp
Kelly, Jack L.	SP5	92B1R	Med Lab Sp
Lipp. Gary	SP5	91T20	Animal Care Sp
Mead, Michael	PFC	92B1R	Med Lab Sp
		91T10	Animal Care Sp
		92B1R	Med Lab Sp
	GS12	00401	Research Immunologist
	GS11	00334	Computer Sp
	GS9	01320	Chemist

C. Staffing (continued)

Name	Rank	MOS	Title
Ayala, Eleanor F.	GS9	00644	Medical Technologist
	GS9	00404	Biological Technician
Hansen, Linda M.	GS7	00645	Medical Technician
Chapa, Isidoro	GS7	00645	Medical Technician
Bratten, Dodie	GS7	01087	Editorial Assistant
	GS4	00322	Clerk Typist

D. Funding

Type	Fiscal Year 80	Fiscal Year 81
Civilian personnel to incluue benefits	72,855.00	60,074.00
Consumable supplies	58,362.87	120,891.00
Civilian contracts to include consultants	13,405.60	14,408.70
TDY	4,830.00	13,265.00
Publications	4,961.63	4,665.00
Noninvestment equipment (Minor MEDCASE)	-	55,078.38
Other OMA		
OMA TOTAL	154,415.10	268,382.08
MEDCASE	37,894.25	151,381.42
Other		
Military	157,000.00	279,317.00
TOTAL	349,309.35	699,080.50

E. Progress

Protocol Disposition FY 81

	Terminated	Transferred	Completed	Ongoing to FY 82
FY 73	-	-	1	0
FY 74	-	-	-	1
FY 75	-	-	-	1
FY 76	-	-	1	0
FY 77	-	-	-	3
FY 78	-	-	-	4
FY 79	3	-	2	6
FY 80	6	-	6	12
FY 81	1	1	12	53
	10	1	22	80

E. Progress (continued)

Group Protocol Disposition FY 81

	Terminated	Completed	Ongoing FY 81
SWOG	-	24	71
GOG	-	1	23
PVSG	1	1	3
POG	2	5	17
	3	31	114

F. Problems

Most of our problem areas remain the same though there has been some encouraging progress in some areas. Our biggest problem continues to be adequate laboratory and administrative space. At the time the department moved into its present facilities, there were five assigned personnel occupying approximately 1850 square feet of space to work on 12 in-house protocols. At the present time, there are 23 assigned personnel working on 50 protocols in the same 1850 square feet. The addition of more equipment during the year has cut down on available work space.

Our desperate need for an animal facility was lessened somewhat by obtaining an old barracks-type building that was scheduled for destruction. Although it does not meet AALAC standards, it gives the department some capability for animal housing and operating room facilities. Our animal facility and space problems can be effectively resolved only with the completion of a major construction project for a separate building originally scheduled for 1984 but currently scheduled for 1987.

A total of 28 requirements have been approved for the Department and 22 authorizations have been allocated which has improved our personnel problems somewhat. Our principal remaining difficulty in personnel is in identifying and obtaining qualified military personnel. Severe shortages in Med Lab Specialists (92B), Biological Research Assistants (01H), Animal care Specialists (91T) and Veterinarians have taken their toll in keeping many of our positions empty.

TABLE OF CONTENTS

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Code:

C - Completed
O - Ongoing
T - Terminated
Tr - Terminated

P - Published
PR - Presentation

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Brooke Army Medical Center
Fort Sam Houston, Texas 78234
DEPARTMENT OF CLINICAL INVESTIGATION

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DEPARTMENT OF CLINICAL INVESTIGATION

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DEPARTMENT OF THE ARMY
Brooke Army Medical Center
Fort Sam Houston, Texas 78234
DEPARTMENT OF CLINICAL INVESTIGATION

PRESENTATIONS

OFFICE OF THE COMMANDER

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DEPARTMENT OF CLINICAL INVESTIGATION

Allen, R.C. Oxygen-dependent Streptococcus faecalis chemiluminescence: The importance of metabolism and medium composition. Amer. Soc. of Microbiologists, Dallas, TX, 1-6 Mar 81. (C)

Allen, R.C., Guest Lecturer, Rush Medical Center, Chicago, IL. (C)

Allen, R.C., Guest Lecturer, Department of Microbiology, University of Texas, Austin, TX., Sep 81. (C)

Allen, R.C. Direct Quantification of Phagocyte Oxygenation Activity in Whole Blood: A Chemiluminigenic Probe Approach. XI International Congress of Clinical Chemistry, Vienna, Austria, 30 Aug-5 Sep 81. (C)

Allen, R.C., Guest Lecturer, European Society for Biochemistry, Auctenhausen, Germany, 8 Sep 81. (C)

Allen, R.C., Guest Lecturer, Brussels, Belgium, 12 Sep 81. (C)

Anderson, J.H. Clinical Evaluation of Botulinum Toxoids. Biological Aspects of Botulism Conference, Fort Detrick, MD, 17 Mar 81. (C)

Anderson, J.H. Glucose Induced Hyperinsulinism during Endotoxemia in Dogs - A Possible Mechanism. Annual Meeting of Southern Sugar Club, Kiawah Island, Charleston, SC. 25 Feb-3 Mar 81. (C)

Anderson, J.H. Glucose Induced Hyperinsulinism during Endotoxemia in Dogs - A Possible Mechanism. American Diabetes Assoc., Endocrine Society, and Assoc. of Military Endocrinologists, Cincinnati, OH, 13-19 Jun 81. (C)

Burleson, D.G. Separation of Guinea Pig Peritoneal Exudate Cells on Percoll Gradients: Comparison of Morphology and Oxygenation Activity in Response to Various Stimuli. Federation of Societies for Experimental Biology, Atlanta, GA, 15 Apr 81. (C)

Burleson, D.G. Functional Differentiation of Peritoneal Exudate Macrophages and Polymorphonuclear Leukocytes: An Approach Based on Chemiluminigenic Probing of Phagocytic Oxygenation Response to Various Stimuli. Perspectives in Endocrinology and Clinical Chemistry. Florence, Italy, 7 Jul 81.

Hunter, E.J. Chemiluminescence Following Exposure of Anaerobic Broth Medium to Atmospheric Oxygen: The Role of O_2^--Redox Reactions. Amer. Soc. of Microbiologists, Dallas, TX, 1-6 Mar 81. (C)

Madonna, G.S. Immunoglobulin-Mediated Opsonification of Shigella sonnei Phase I: Functional Study Based on Granulocyte Chemiluminescence. Amer. Soc. of Microbiologists, Dallas, TX, 5 Mar 81. (C)

Stevens, D.L. Effects of Phospholipase C and Theta Toxin from C. Perfringens upon Human Neutrophil Functions. Amer. Federation for Clinical Research, 25-27 Apr 81. (C)

DEPARTMENT OF MEDICINE

Cardiology Service

Bird, J.J. Subvalvular Gradients in Aortic Stenosis Without Subvalvular Obstruction. 53rd Scientific Sessions of the American Heart Association, Miami, FL, Nov 80. (C)

Craig, W.E. Evaluation of Isovolumic Relaxation in Normal Man During Rest, Exercise, and Isoproterenol Infusion. 53rd Scientific Sessions of the American Heart Association, Miami, FL, Nov 80. (C)

Murgo, J.P. Relaxation Abnormalities in Hypertrophic Cardiomyopathies. 53rd Scientific Sessions of the American Heart Association, Miami, FL, Nov 80. (C)

Murgo, J.P. Invited Speaker: Core Curriculum Symposium on Heart Sounds and Murmurs. 29th Annual Scientific Sessions of the American College of Cardiology. San Francisco, CA, Mar 81. (C)

Murgo, J.P. Chairman, Clinical and Basic Muscle Physiology, Coronary Blood [illegible] and Echocardiography. Annual Sessions of the American Society of Clinical Investigation, San Francisco, CA, Apr 81. (C)

[illegible], A. Pulmonic Stenosis in Atrioventricular and Ventriculoarterial Discordance with an Intact Ventricular Septum and Anterior Aorta. 10th Annual [illegible] of the Association of Army Cardiology, Fort Sam Houston, TX, May 81.

[illegible], R.J. The Effects of [illegible] Second Heart Sound Splitting in Coronary Artery Disease. 10th Annual Session of the Association of Army Cardiology. Fort Sam Houston, TX, May 81. (C)

[illegible], S. Second Heart Sound Dynamics in Atrial Septal Defects (ASD). 10th Annual Session of the Association of Army Cardiology. Fort Sam Houston, TX, May 81. (C)

[illegible], D.F. Exercise Induced Abnormalities of Left Ventricular Relaxation in Coronary Artery Disease. 10th Annual Session of the Association of Army Cardiology, Fort Sam Houston, TX, May 81. (C)

Bird, J.J. Left Ventricular External Work Loss in Valvular Aortic Stenosis: Correlation with Severity. 10th Annual Session of the Association of Army Cardiology, Fort Sam Houston, TX, May 81. (C)

Schatz, R.A. The Effect of Arterial Pressure Reflections on Myocardial Supply-Demand Dynamics. 10th Annual Session of the Association of Army Cardiology, Fort Sam Houston, TX, May 81. (C)

Dermatology Service

Wilson, R.K. Vulvar Hyperpigmentation Case Presenting as Pigmented Bowen's. San Antonio Dermatological Society Meeting, San Antonio, TX, 2 Oct 80.

Babcock, W.S. Case Presentation Zola Cooper Memorial CPC, Southern Medical Association Meeting, San Antonio, TX, 17 Nov 80.

Salasche, S.J. Malignant Melanoma - Diagnosis and Treatment. Texas Association of Physician Assistants, Austin, TX, 18 Nov 80.

Salasche, S.J. Metastatic Basal Cell Carcinoma. American College of Chemosurgery Annual Meeting, New York City, NY, 4 Dec 80.

Fulk, C.S. Reticulate Acropigmentation. American Academy of Dermatology, New York City, NY, 6 Dec 80.

Cook, J.R. Lichenoid Dermatitis and Thrombocytopenic Purpura Associated with Gold Therapy for Rheumatoid Arthritis. American Academy of Dermatology, New York City, NY, 6 Dec 80.

Lewis, C.W. Dermatology in the Tropics. Global Medicine Course. Brooks Aerospace Center, San Antonio, TX, 20 Apr 81.

Salasche, S.J. Morpheaform Basal Cell Carcinoma. 6th Annual Uniformed Services Dermatology Seminar, Bethesda, MD, 8 May 81.

Babcock, W.S. Moderator of Clinical Pathology Conference. 6th Annual Uniformed Services Dermatology Seminar, Bethesda, MD, 7 May 81.

Krauss, E.W. Case Presentation - Idiopathic Hyperpigementation of the Vulva. Continuous Vulvar and Vaginal Disease Course, New York City, NY, 16 May 81.

Clemons, D.E. Atrophie Blanche. 21st Annual Armed Forces Institute of Pathology Lectures, Washington DC, 21 May 81.

Clemons, D.E. Acrokeratosis Verruciformis. 21st Annual Armed Forces Institute of Pathology Lectures, Washington DC, 21 May 81.

Fulk, C.S. Under Agarose Chemotaxis by Psoriatic Leukocytes. Third International Symposium on Psoriasis, Stanford University Medical Center, Stanford, CA, 13-17 Jul 81. (C)

Lewis, C.W. New Treatment of Porphyria. Dallas Dermatological Society Meeting, Dallas, TX, 25 Aug 81.

Nephrology Service

Wright, L.F. Home Dialysis in an Army Hospital. American Society of Nephrology, Washington DC, Nov 81.

Oncology Service

McCracken, J.D. Oat Cell Carcinoma of the Lung. Oregon Society Clinical Oncology, Portland, OR, 29 Jan 81.

McCracken, J.D. Chemotherapy of Pancreatic Cancer. ACS Mid-Winter Symposium, Portland, OR, 30 Jan 81.

McCracken, J.D. Chemotherapy of Gastric Cancer. ACS Mid-Winter Symposium, Portland, OR, 30 Jan 81.

McCracken, J.D. Chemotherapy of the GI Malignancies. St. Vincent's Hospital Cancer Conference, Bridgeport, Conn., 2 Feb 81.

McCracken, J.D. Treatment of Solid Tumors. Current Concepts in Hem/Onc, USA, Washington DC, 3 Feb 81.

Cowan, J.D. Update on Stem Cell Assays: Testing New Agents. Current Concepts in Hem/Onc, USA, Washington DC, 3 Feb 81.

Shildt, E.A. Immunization of Patients with Neoplasia. Current Concepts in Hem/Onc, USA, Washington DC, 4 Feb 81.

Madden, S.A. Treatment of Metastatic Colorectal Cancer to Liver with Intrahepatic FUDR or 5FU or Mitomycin in Previously Untreated Patients. Current Concepts in Hem/Onc, USA, Washington DC, 4 Feb 81.

[redacted], C.M. Changes of Coagulation and Complement in Snake Bites. Current Concepts in Hem/Onc, USA, Washington DC, 5 Feb 81. (C)

[redacted]Cracken, J.D. Combination Chemotherapy, Radiotherapy and BCG Immunotherapy in Limited Small Cell Carcinoma of the Lung. XIIth International Congress of Chemotherapy, Florence, Italy, 21 Jul 81.

[redacted], J.D. U.S. Experience with Mitoxantrone. XIIth International Congress of Chemotherapy, Florence, Italy, 21 Jul 81.

Livingston, R.B., McCracken, J.D., Chen, T. Isolated Pleural Effusion in Small Cell Carcinoma: A Favorable Prognostic Group. AACR, 81.

Cowan, J.D., McCracken, J.D., Von Hoff, D.D. Multiple Sample Drug Sensitivity Concordance in the Human Tumor Cloning System. ASCO, 1981.

Von Hoff, D.D., Page, C., Cowan, J. Prospective Clinical Trial of a Human Tumor Cloning System. Proc. Amer. Assoc. Cancer Res. and ASCO, 1981.

Cowan, J.D., Coltman, C.A., Von Hoff, D.D. Use of the Human Tumor Cloning System to Evaluate the Aerobic Cytotoxic Activity of Misonidazole. Proc. Amer. Assoc. Cancer Res. and ASCO, 81.

Harvey, W.B. The Oncologist and Interventional Radiologist Team: New Developments in Patient Care. Fourth Annual Osteopathic Hospital of Wichita Summer Postgraduate Course, Wichita, KA, 25-27 Jun 81.

Pulmonary Disease Service

Fetters, L.J. Surgery in Bullous Lung Disease. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 19 Jan 81.

Woodward, T.A. Upper Airway Obstruction Secondary to Enlarged Tonsils. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 19 Jan 81.

Matthews, J.I. Exercise Testing in the Evaluation of Pulmonary Sarcoidosis. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

Martin, M.R. The Unilateral Hyperlucent Lung. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

Sullivan, C.J.P. Squamous Cell Carcinoma. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

Brown, P.P. Pulmonary Strongyloidiasis. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

[illegible] J, T.E. Two Cases of Gravidas with Ventriculo-Peritoneal Shunts. AFD-ACOG, Orlando, FL, 5-10 Oct 80.

Powell, T.F. Treatment of Premature Labor with Terbutaline. AFD-ACOG, Orlando, FL, 5-10 Oct 80.

DEPARTMENT OF PEDIATRICS

Wilson, L.O. The Computerized Triage of Pediatric Patients. University Association of Emergency Medicine, San Antonio, TX, Apr 81. (C)

Wilson, L.O. Computeres in a Pediatric Acute Care Facility. 5th International Congress of Emergency Surgery, Brighton, England, Jun 81. (C)

DEPARTMENT OF PSYCHIATRY

Myers, L.S. DSM-III Organic Mental Disorders. AMEDD Psychiatry Conference, El Paso, TX, 80.

DEPARTMENT OF RADIOLOGY

Telepak, R.J. Rotating Slanthole and 7-Pinhole Tomography in Nuclear Medicine. Pacific Northwest Chapter Society of Medicine Annual Meeting, Seattle, WN, 28 Mar 81.

Telepak, R.J. Fourier Phase Analysis of Gated Bloodpool Scans in Nuclear Medicine. Pacific Northwest Chapter Society of Medicine Annual Meeting, Seattle, WN, 29 Mar 81.

Telepak, R.J. I-125 Fibrinogen Studies in Carotid Ulcer Disease. AMEDD Radiology Symposium, Walter Reed Army Medical Center, Washington DC, 27 May 81.

Telepak, R.J. Nuclear Cardiology in the Community Hospital. Harlingen Medical Society, Harlingen, TX, 29 Jun 81.

Telepak, R.J. Nuclear Cardiology in the Community Hospital. San Angelo Medical Society, San Angelo, TX, 15 Sep 81.

DEPARTMENT OF SURGERY

Anesthesiology and Operative Service

Weddel, S.J. Serum Levels Following Epidural Administration of Morphine and Correlation with Relief of Post Surgical Pain. American Society of Anesthesiology, St. Louis, MO, Oct 80.

Gooding, D.E. Light Wand Intubations. Department of Anesthesia, Bay City Memorial Medical Center, Panama City, FL, 26 Jan 81.

General Surgery Service

Stallings, R.J. Fibromuscular Dysplasia Involving Internal Carotid Arteries: A Six-Year Experience. 33rd Annual Southwestern Surgical Clinic Congress, [illegible], CA, 2-7 May 81.

Stallings, R.J. An Approach to Rectal Procidentia (The Ripstein Procedure). Gary P. Wratten Surgical Symposium, San Antonio, TX, 29 Apr-1 May 81.

[illegible], K.L. Review of Colorectal Cancer in Patients Under 40. 33rd [illegible] Southwestern Surgical Clinical Congress, Monterey, CA, 4-7 May 81.

Safford, K.L. Upper Gastrointestinal Bleeding: The Brooke Army Medical Center Experience. Gary P. Wratten Surgical Symposium, San Antonio, TX, 29 Apr-1 May 81.

Deal, V.P. Arteriovenous Fistula: A Historical Review. Gary P. Wratten Surgical Symposium, San Antonio, TX, 29 Apr-1 May 81.

Spebar, M.J. Hiroshima Revisited. Gary P. Wratten Surgical Symposium, San Antonio, TX, 29 Apr-1 May 81.

Spebar, M.J. Hiroshima Revisted: A Medical Prospective. Medical Effects of Nuclear Weapons Course, Bethesda, MD, 13 May 81.

Spebar, M.J. Changing Trends in causalgia. 33rd Southwestern Surgical Clinical Congress, Monterey, CA, 4-7 May 81.

Spebar, M.J. Changing Trends in Causalgia. Annual Meeting of the Society of Military Vascular Surgeons, Bethesda, MD, 11 Dec 80.

Spebar, M.J. Medical Aspects of Nuclear Warfare. Distinguished Visiting Professor Series, Uniformed Services University of Health Sciences, Bethesda MD, 27 Aug 81.

Spebar, M.J. Perioperative Heparin Prophylaxis of Deep Venous Thrombosis in Vascular Surgery Patients. 33rd Annual Southwestern Surgical Clinical Congress, Monterey, CA, 4-7 May 81.

Walters, M.J. Emergency Treatment of Burn Patients. U.S. Air Force Medical RED FLAG, Oct 80.

Walter, M.J. Emergency Treatment of Burn Patients, U.S. Air Force RED FLAG, San Antonio, TX, Mar 81.

Walters, M.J. Emergency Treatment of Burn Patients. U.S. Air Force Medical RED FLAGG, Germany, Sep 81.

Rosenthal, D. Anatomy of the Anal Sphincter. Spring Meeting, Walter Reed Army Medical Center, 3 Apr 81.

Rosenthal, D. Management of Perforated Rectal Prolapse. Texas Colorectal Society Meeting, Dallas, TX, Jun 81.

Rosenthal, D. Rectal Prolapse and Procidentia. Guest Lecturer, Surgical Grandrounds, South Texas School of Medicine, San Antonio, TX, 21 Aug 81.

Spebar, M.J. Improved Survival with Aggressive Surgical Management of Non-candidal Fungal Infections. 14th Annual Meeting of the American Burn Association, Boston, Mass., 12-15 May 81.

Spebar, M.J. Coccidioidomycosis of the Burn Wound. 14th Annual Meeting of the American Burn Association, Boston, Mass., 12-15 May 81.

Neurological Surgery Service

Gendell, H.M. The CNS Role in Arterial Hypertension. Congress of Neurological Surgeons, Houston, TX, 6-12 Oct 80.

Harris, R.D. in Vitro Assessment of Human Pituitary Tumor Neoplastic Activity. International SEM Symposium, University of Nijmegan, The Netherlands, 13-16 Sep 81.

Ophthalmology Service

Brennan, M.W. Traumatic Optic Neuropathy: Mechanisms and Management. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Glover, A.T. Intraocular Lens Implantation in the Residency Program at Brooke. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81. C)

Mein, C.E. Planned Extracapsular Cataract Extraction and Posterior Chamber Intraocular Lens Implantation. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81. (C)

Zervas, J. Pierre Robin Syndrome: A Case Presentation and Discussion. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Gearhart, J. Over-Refraction Made Easy. Alamo City Opthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Davitt, W.F. Ocular Complications in Craniofacial Fibrous Dysplasia. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

San Martin, A. Contact Lens Associated Giant Papillary Conjunctivitis. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Whitsitt, L.S. Graves Orbitopathy - Surgical and Nonsurgical Management. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

[illegible]sten, D.A. Foveal Macular Retinitis. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 [illegible] 81.

[illegible] D.G. Management of "Lost" Lens Nucleus into Vitreous. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

[illegible]auidin, W.M. Bietti's Tapetoretinal Degeneration without Marginal Corneal Dystrophy: Crystalline Retinopathy. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Orthopaedic Service

Hochreiter, G.C. A Case Report of Mesenchymal Chondrosarcoma of the Pelvis and Its Treatment with a Review of the Literature. Society of Military Orthopaedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.

Thomas, S.R. CET Scan, A New Kind of CAT. Society of Military Orthopaedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.

Thomas, S.R. Experience with the TARA Hip Resurfacing at Brooke Army Medical Center. Society of Military Orthopaedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.

Spires, T.D. Congenital Scoliosis Due to a Single Hemivertebra. Society of Military Orthopaedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.

Thomas, S.R. Symposium: Current Status on Joint Replacement. Society of Military Orthoapedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.

Thomas, S.R. TARA Hip Resurfacing Experience at Brooke Army Medical Center. American College of Surgeons, Galveston, TX, 29-31 Jan 81.

Baker, C.L. Acute Posterior Cruciate and Posterolateral Instability of the Knee. American Orthopaedic Society for Sports Medicine, Las Vegas, Nev., 25-26 Feb 81.

Biomechanics and Its Relation to Sports Medicine of the Foot and Ankle. Bexar County Physiatrist Association, San Antonio, TX, Feb 81.

Podiatry and Its Role in Management of Trauma to the Foot and Ankle. Army Physical Therapy Annual Seminar, San Antonio, TX, Mar 81.

Anatomy, Examination and Classification of Rotational Instabilities of the Knee. Texas Physical Therapy Association, University of Texas Health Science Center, San Antonio, TX, 28-29 Mar 81.

Reconstructive Surgery for Chronic Anterolateral and Posterolateral Instability of the Knee. Texas Physical Therapy Association, University of Texas Health Science Center, San Antonio, TX, 28-29 Mar 81.

Principles of a Functional Knee Rehab Program. Texas Physical Therapy Association, University of Texas Health Science Center, San Antonio, TX, 28-29 Mar 81.

Baker, C.L. Acute Posterior Cruciate and Posterolateral Instability of the Knee. Society of Air Force Clinical Surgeons Meeting, San Antonio, TX, 15 Apr 81.

Subtalar Subluxation - Its Diagnostic Criteria and Treatment. Bandera Podiatry Seminar, University of Texas Health Science Center, San Antonio, TX, Apr 81.

Baker, C.L. Modern Pentathlon. American Orthopaedic Society for Sports Medicine, Hyatt Lake, Nev., 21-26 Jun 81.

Prevention and Care of Football Injuries. Mothers' Club, Cole High School, San Antonio, TX, 14 Sep 81.

Knee Instability. U.S. Army Medical Department Activity, West Point, NY, 17-19 Sep 81.

Cardiothoracic Surgery Service

Collins, G.J. Renovascular Hypertension. Vascular Symposium, St. Catherine's Hospital, Garden City, KA, 2 Nov 81.

Collins, G.J. Cardiovascular Insufficiency. Vascular Symposium, St. Catherine's Hospital, Garden City, KA, 2 Nov 81.

Collins, G.J. Venous Disorders: Medical and Surgical Management. Vascular Symposium, St. Catherine's Hospital, Garden City, KA, 2 Nov 81.

Schuchmann, G.F. Tetralogy of Fallot. William Beaumont Army Medical Center, El Paso, TX, 21 Nov 80.

Schuchmann, G.F. Coronary Artery Disease. William Beaumont Army Medical Center, El Paso, TX, 21 Nov 80.

Collins, G.J. Renovascular Hypertension. Military Vascular Surgeons Seminar, Bethesda, MD, 11 Dec 80.

Collins, G.J. Popliteal Artery Entrapment Syndrome. Southern Association of Vascular Surgery, Dorado Beach, PR, 29 Jan 81.

Schuchmann, G.F. Current Concepts in Surgical Treatment of Carcinoma of the Esophagus. Gary P. Wratten Surgical Symposium, San Antonio, TX, 29 Apr 81.

Schuchmann, G.F. Moderator of the Clinical Session at the 10th Annual Session of the Association of Army Cardiology, Brooke Army Medical Center, Fort Sam Houston, TX, 20 May 81.

Hall, R.V. Combined Valve Replacement and Coronary Artery Bypass in the Elderly. 10th Annual Session of the Association of Army Cardiology, Brooke Army Medical Center, Fort Sam Houston, TX, 20 May 81.

Hall, R.V. Current Status of Prosthetic Cardiac Valve Replacement. TV Lecture, San Antonio, TX, 27 Jul 81.

Peake, E.B. Surgical Management of Empyema Lung Abscess and Bronchopleural Fistula. TV Lecture, San Antonio, TX, 21 Sep 81.

Urology Service

Pettigle, E.B. Combined External Beam Radiotherapy and Pelvic Lymphadenectomy in the Management of Carcinoma of the Prostate. 28th Annual James C. Kimbrough Urological Seminar, San Diego, CA, 17-21 Nov 80.

Gil, F.M. Intrascrotal Pathology: Comparison Among Different Diagnostic Techniques. 28th Annual James C. Kimbrough Urological Seminar, San Diego, CA 17-21 Nov 80.

Spiegel, R.S. Familial Testicular Tumors. 28th Annual James C. Kimbrough Urological Seminar, San Diego, CA, 17-21 Nov 80.

Spence, C.R. Peyronie's Disease: Results of Treatment with Rectus Fascia Graft. 28th Annual James C. Kimbrough Urological Seminar, San Diego, CA, 17-21 Nov 80.

Gangai, M.P. Peyronie's Plaque: Excision and Graft Versus Incision and Stent. 28th Annual James C. Kimbrough Urological Seminar, San Diego, CA, 17-21 Nov 80.

Spence, C.R. Urological Diagnostic Studies. Regional Urology Workshop, San Antonio, TX, 23 Oct 80.

Spence, C.R. Urological Diagnostic Studies. Gonzalez County Medical Society, Gonzalez, TX, 24 Jul 81.

Gangai, M.P. Case Presentation at the Texas Urologic Society Meeting, Kerrville, TX, 9-11 Apr 81.

PHARMACY SERVICE

Sikora, R.G. An Analysis of the Change in Work Patterns Following Installation of an Inpatient Pharmacy Computer System. American Pharmaceutical Association Meeting, San Antonio, TX, 11 Nov 80.

Kembold, J.M. An Experience Report in Pharmacy Patient Discharge Consultations. Texas Society of Hospital Pharmacy, San Antonio, TX, Mar 81.

SOCIAL WORK SERVICE

Allen, J.D. Sexual Problems of Adolescents. National Association of Pediatric Nurse Practitioners Conference, 11 Oct 80.

Nolan, F.J. Management of Domestic Violence in the Military. National Conference for Family Violence Researchers, Durhan, NH, 21-25 Jul 81.

Allen, J.D. Shadow at the Table: The Absentee Father. Biennial Symposium, Family Service Association of America, San Antonio, TX, 11 Sep 81.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-25-78	Status: Ongoing

TITLE:

Determination of Opsonizing Antibody in People Receiving Polyvalent Pneumococcal Vaccine

Start Date: 30 May 78		Est Comp Date: Jul 82
Principal Investigator Robert C. Allen, M.D., Ph.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation		Associate Investigators: Deborah J. Hunter, SP 5
Key Words: Pneumococcal vaccine Opsonification Streptococcus species Chemiluminescence		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1808	Periodic Review Results: Continue

Objective: To Determine the serum opsonizing activity in selected patients in response to a polyvalent pneumococcal vaccine.

Technical Approach: Pre- and postimmunization sera were obtained from patients undergoing immunization against Streptococcus pneumoniae using polyvalent pneumococcal vaccine (Pneumovax^{R} MSD). These sera are being tested for opsonic activity directed against a number of serotypes of Streptococcus pneumoniae as well as other streptococcal species. A highly sensitive chemiluminescent assay has been developed for quantification of neutrophil (PMNL) leukocyte O_2-redox metabolism, and this technique is being applied to the quantification of the level of opsonification for these sera.

Progress: Preliminary testing of selected pre- and postimmunization sera has been carried out. At present, the major difficulty is the preparation, stabilization, and quantification of the type-specific streptococcal antigen so as to insure uniformity of measurements.

In the course of investigation, important observations have been made with regard to interaction of streptococcal metabolic products, such as H_2O_2 and lactic acid, with PMNL myeloperoxidase. These observations have led to a collaborative study with Drs P. G. Quie and E. L. Mills of the Department of Pediatrics of the University of Minnesota. The results of this research have been published in the Journal of Infectious Disease 144:344-348, 1981.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-5-79	Status: Ongoing

TITLE:

Assessment of Opsonic Capacity and Phagocyte Functionality in Microliter Quantities of Whole Blood

Start Date: 5 Jan 79	Est Comp Date: Jul 82
Principal Investigator Robert C. Allen, M.D., Ph.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Deborah J. Hunter, SP5 Jack Kelly, SP5
Key Words: Complement Immunoglobulin Chemiluminigenic probes Oxygen Metabolism	

Cumulative MEDCASE Cost:	Est Accumulative OMA Cost: $24,143	Periodic Review Results: Continue

Objective: to research and develop a rapid, objective, and quantitative approach to the assessment of phagocyte activity in microliter quantities of whole blood by introduction of high quantum yield oxidizable substrate and use of photomultiplication techniques to quantitate chemiluminescence (luminescence resulting from chemical reaction).

Technical Approach: The use of two difficult high quantum yield, oxidizable substrates for quantification of phagocyte O_2-redox activity in whole blood has been achieved. Both luminol, 5-amino-2,3-dihydro-1,4-phthalazinedione, and lucigenin, 10,10'-dimethly-9,9'-biacridinium dinitrate, have been employed in this manner. Other substrates are also under investigation. A technique for quantification of serum opsonic capacity, based on the rate of activation of PMN O_2-redox metabolism has also been established using chemiluminigenic probes.

Progress: Chemiluminigenic probing has been developed into an ultra sensitive method for continuous and nondestructive assessment of oxygenation activity of PMNL and monocytes. The results of differential probing, using probes of different physical characteristics and chemical reactivities, indicate that the oxygenation responses of PMNL and monocytes differ with regard to the type of stimulus employed. The technique allows measurement of PMNL and monocyte function in submicroliter quantities of whole blood.

With regard to the study of opsonification, important observations have been made on the roles of alternative and classical pathway complement, IgG and IgM in the mechanisms of bacterial opsonification. Furthermore, the chemiluminigenic probe approach shows promise as a method for detection of circulating immune complexes.

Detail Summary Sheet

Date: 1 Oct 81 | Proj No: C-8-79 | Status: Ongoing

TITLE:

The Measurement of Cyclic Nucleotide Levels in Purified Populations of Lymphocytes Incubated with Mitogens.

Start Date: 6 Feb 79	Est Comp Date: Jun 82
Principal Investigator David G. Burleson, Ph.D., MAJ, MSC	Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation	Associate Investigators: John H. Sinegal, SSG
Key Words: Cyclic nucleotide levels T and B cells Mitogens	

Accumulative MEDCASE Cost: $93,000.00	Est Accumulative OMA Cost: $6,137	Periodic Review Results: Continue

Objective: To purify guinea pig lymphocytes on density gradients into functional subpopulations and measure intracellular levels of cyclic AMP and cyclic GMP after incubation of the purified cells with the mitogens for T and B Cells.

Technical Approach: Guinea pig lymph node cells are separated into seven populations using discontinuous gradients of 40-75% Percoll. The purified cells are exposed to various lectins and at different time periods the cells are lysed with a precipitating reagent and the cyclic nucleotides extracted. The extracts are purified by HPLC and measured by radioimmunoassay. Cyclic AMP and cyclic GMP levels are then correlated with the mitogenicity of the lectin, the time of incubation and the cell type. Cell populations are characterized by Wright's stain and observation under a microscope for morphology and by fluorescent immunoglobulin technique for T and B cell identification.

Progress: No significant progress was made on the project due to the lack of a high pressure liquid chromatograph. A high pressure liquid chromatograph has been obtained, and the development of a purification technique and analysis of samples can now proceed.

Detail Summary Sheet

Date: 1 Oct 81 | Proj No: C-26-79 | Status: Ongoing

TITLE:

Studies on the Opsonization and Phagocytosis of Invasive and Non-invasive Shigella Species by Polymorphonuclear Leukocytes (PMNL).

Start Date: 6 Nov 79	Est Comp Date: Jul 82
Principal Investigator Gary S. Madonna, M.S., CPT, MSC	Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Robert C. Allen, M.D., Ph.D. MAJ, MC Michael M. Lieberman, Ph.D. CPT, MSC
Key Words: Shigella sonnei Polymorphonuclear leukocytes (PMNL) Chemiluminescence (CL)	

Cumulative MEDCASE Cost:	Est Accumulative OMA Cost: $7,000	Periodic Review Results: Continue

Objective: To investigate the roles of nonspecific and specific immunoglobulins and complement in effecting opsonization and microbicidal action of PMNL against various enteric invasive bacteria.

Technical Approach: Bacterial cultures are grown in BHI broth and opsonized with serum from rabbits immunized with the given strain of bacteria. Serum is separated into IgG, IgM and IgA using either Sepharose 6B or DEAE Sephacil column chromatography. PMNL are separated from blood by either Dextran sedimentation or Percoll. Stimulation of PMNL O_2-redox metabolism as required for oxidative killing is measured by a chemiluminescent technique using luminol as a chemilumigenic probe. Measurement of this PMNL-CL is accomplished using a Beckman LS 250 scintillation counter. Killing of organisms is measured at the end of each CL run by plating samples with appropriate controls on nutrient agar, incubating the plates overnight at 37°C, counting bacterial colonies and calculating an antibacterial index for each group of samples.

Progress: A method which simultaneously measures PMNL-CL and bacterial killing has been developed. This method will be used to analyze immunoglobulin and complement opsonic requirements necessary for stimulation of PMNL microbicidal activity and whether this activity results in decreased viability of the microbe. As such, Shigella sonnei phase I and phase II, Shigella flexneri 2a and O forms and perhaps various Salmonella strains will be studied. During the course of development of this method we have found that IgG to opsonize S. sonnei phase I in the absence of complement whereas specific IgM requires the action of complement.

Detail Summary Sheet

Proj No: C-38-79 Status: Ongoing

Title: The Effect of Prostaglandin Synthesis Inhibitors on in vitro Suppressor Cell Activity in Lymphocytes from Patients with Common Variable Agammaglobulinemia.

Start Date: Sep 79	Est Comp Date: Oct 82
Principal Investigator David G. Carlsson, Ph.D., MAJ, MSC	Facility Brooke Army Medical Center
Dept/Div: Department of Clinical Investigation	Associate Investigators: Michel N. Laham, M.D., MAJ, MC Charles M. Loyd, SFC
Key Words: Agammaglobulinemia T-cell suppressor	

Cumulative MEDCASE	Est Accumulative OMA Cost: $6,073	Periodic Review Results: Continue

Objective: To test the in vitro activity of prostaglandin synthesis inhibitors, such as indomethacin, on T-cell suppressor activity found in lymphocytes from patients with common variable agammaglobulinemia. The reversal of suppressor activity on immunoglobulin cells by such inhibitors may indicate possibilities for an effective therapeutic drug for this immunodeficiency.

Approach: Human peripheral blood lymphocytes (HPBL) from normal individuals, patients with common variable agammaglobulinemia, or HPBL subjected to a suppressor cell stimulant are incubated in the presence of pokeweed mitogen and selected cultures in the presence of immunomodulating drugs. After a 48 hour culture, the cells are harvested and plated on slides in agar. Immunoglobulin cells are detected using the reverse hemolytic plaque assay. This involves plating HPBL with sheep red blood cells coated with protein A. The agar coated slides containing the cells are incubated with anti-human immunoglobulin and complement to develop the plaques. The plaques are then counted under a low power microscope. Increased numbers of plaques indicate increased lymphocyte suppressor activity. Plaque counts of normal patient cultures, suppressed-normal patient cultures are compared to determine the presence of suppressor cell activity. Suppressed cultures incubated with immunomodulating drugs are evaluated for release from suppressor activity.

Progress: Due to the shortage of agammaglobulinemic patients admitted to BAMC, this study has focused on studying the effects of immunomodulating drugs on in vitro artificially suppressed cultures. Development of a method to isolate T suppressor cells from these populations is also being developed. A preliminary report published as an abstract in Clinical Research indicated that several drugs that induce lupus symptoms were able to stimulate increased numbers of plaques after incubation with cells in culture. Further studies have also shown that steroids have a large capacity to stimulate plaque formation.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-4-80	Status: Ongoing

TITLE:

The Development of a Pseudomonas aeruginosa Vaccine for Laboratory Animals, Phase II.

Start Date: 10 Jan 80		Est Comp Date: Jan 83
Principal Investigator Michael M. Lieberman, Ph.D., CPT, MSC		Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation		Associate Investigators: Karen Wolcott, SP5 Fatima Ebrahim, SSG Eleanor Ayala, DAC
Key Words: Pseudomonas aeruginosa Vaccine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $8,870	Periodic Review Results: Continue

Objective: To develop a safe and effective, multivalent, Pseudomonas aeruginosa vaccine and hyperimmune globulin for laboratory animals.

Technical Approach: *Ribosomal vaccines are prepared as described previously* (JBC 77) from all available serotypes of P. aeruginosa. Rabbits are divided into two groups and each group is immunized with half the total number of vaccine preparations. (Prior to immunization the rabbits are bled to obtain pre-immune sera.) After the immunization schedule, rabbits are bled for the immune sera. Groups of mice are injected with the multivalent antisera and then challenged with live cultures of randomly chosen clinical isolates of P. aeruginosa. Mice are scored for percentage of survivors for each challenge dose. The percentage of clinical isolates of Pseudomonas against which statistically significant protection was achieved by the multivalent anti-sera is calculated.

Progress: Ribosomes were dissociated into 30S and 50S ribosomal subunits by dialysis against buffer containing 10^{-3}M MC^{++} and the subunits separated by ultracentrifugation through a sucrose density gradient. These ribosomal subunits were shown to contain a protective antigen, since antisera raised against the isolated subunits are capable of passive transfer of protection. To determine if a relationship existed between the ribosomal vaccine and outer membrane protein (OMP), a preparation of OMP was made from P. aeruginosa and used to immunize rabbits. The following properties of the antisera to OMP were found: 1) antisera to OMP was capable of passive protection of mice against live Pseudomonas, 2) antisera to OMP showed serological reactivity with ribosomal subunits using a complement fixation assay, 3) antisera to OMP also precipitated with unfractionated ribosomal vaccine in ouchterlony. The above results suggest relationship exists between a protective antigen associated with ribosomes and an outer membrane protein(s).

Detail Summary Sheet

Date: 1 Oct 81 Proj No: C-4-81 Status: Ongoing

TITLE:

Chemiluminescence (CL) in Populations of Immunocompetent Cells.

Start Date: 4 Feb 81	Est Comp Date: Dec 82
Principal Investigator David G. Burleson, Ph.D., MAJ, MSC	Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC John H. Sinegal, USG Jack Kelly, SP5
Key Words: Chemiluminescence Immunocompetent cells	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2,557	Periodic Review Results:

Objectives: To quantitate the oxidative metabolic response of stimulated populations of immunocompetent cells isolated from mouse or guinea pig thymus, liver, and lymph nodes using chemilumigenic probes.

To quantitate and characterize the chemiluminescent response from various populations of immunocompetent cells in the presence of cyanide, superoxide dismutase, and catalase.

Methodical Approach: Peritoneal cells from guinea pigs injected IP with sodium caseinate are harvested at 7 days. Macrophages (MP) and polymorphonuclear leukocytes (PMNL) are separated after the harvested cells are subjected to density gradient centrifugation on Percoll. The purified cells are stimulated with various chemical, lectin and phagocytic stimulants as well as various metabolic inhibitors and scavenger enzymes. The resulting oxygenation activity is measured by chemilumigenic probe (CLP) technique. Luminol and DBA are used as CLP and the resulting chemiluminescence (CL) is measured in Beckman liquid scintillation counters modified to be single photon counters.

Progress: The project is approximately one-half completed. Oxygenation activity has distinctive characteristics that are unique for each stimulant and cell type employed. The inhibition of oxygenation activity by enzymes and metabolic inhibitors also give unique patterns depending on PMNL and macrophage stimulant used and cell type. Studies are continuing in an attempt to characterize the nature of the oxygenation activity produced by these cells.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-13-81	Status: Ongoing

TITLE:

Therapeutic Manipulation of Metabolic Endocrine Controls During Infection

Start Date: 11 Mar 81	Est Comp Date: Aug 83
Principal Investigator James H. Anderson, Jr., M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Gerald A. Merrill, CPT, MSC Linda Hansen, DAC
Key Words: Metabolic Endocrine Controls Infection	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2,209	Periodic Review Results: Continue

Objective: To clearly define the mechanisms of hormonal action and metabolic alterations in infectious disease and thus establish the best therapeutic and supportive care for personnel exposed to infectious agents.

Technical Approach: Animals with a variety of induced infections will be studied for glucose tolerance and insulin secretion, binding and effects as well as specific biochemical and physiological function of the islets of Langerhans and cellular insulin receptors on monocytes, hepatocytes and [illegible]ytes.

[illegible]ogress. Continuation of this study at BAMC awaits completion of the [illegible]boratory animal facility.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-14-81	Status: Ongoing

TITLE:

Investigation of the Involvement of Endogenous Opiates in the Development of the Metabolic Pathophysiology of Infection and Endotoxin Shock

Start Date: 11 Mar 81	Est Comp Date: Sep 82
Principal Investigator James E. Anderson, Jr., M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Gerald A. Merrill, CPT, MSC Linda Hansen, DAC
Key Words: Endogenous opiates Endotoxin shock Metabolic pathophysiology	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $10,640	Periodic Review Results: Continue

Objective: To determine the influence of stress released endogenous opiates on hormonal release by the endocrine pancreas (insulin, glucagon, pancreatic polypeptide and somatostatin) as a result of infection or endotoxin shock.

Approach: A. A series of dogs were treated with glucose and/or [illegible] after being given an LD_{70} dose of E. coli endotoxin. The animals were then studied with blood sampling during a six hour post-endotoxin period.

Endogenous opiates will be utilized in in vitro studies with islets of Langerhans isolated from rats to examine insulin synthesis and release.

Progress: A. The animal experiments have been completed and the major task of analysis of the samples is currently underway. Samples will be analyzed for insulin, glucose, glucagon, methionine enkephalin, and β endorphin.

B. Continuation of this part of the study awaits completion of laboratory animal facility.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-15-81	Status: Ongoing

TITLE:

Diabetogenicity of Venezuelan Equine Encephalomyelitis Virus

Start Date: 11 Mar 81		Est Comp Date: Jun 84
Principal Investigator James H. Anderson, Jr., M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation		Associate Investigators: Gerald A. Merrill, CPT, MSC Linda Hansen, DAC
Key Words: Diabetogenicity Venezuelan equine encephalomyelitis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1,360	Periodic Review Results: Continue

Objective: To examine the hypothesis that Venezuelan equine encephalomyelitis (VEE) vaccine virus is diabetogenic in animals.

Technical Approach: Animals inoculated with VEE TC83 vaccine (live virus) are studied for glucose tolerance and insulin secretion as well as specific biochemical and physiological function of the islets of Langerhans.

Progress: Continuation of this study at BAMC awaits completion of the laboratory animal facilty.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-16-81	Status: Completed

TITLE:

Investigation of the Use of Sodium Fluoride for Prevention of Peptidase Degradation of Endogenous Opiates in Plasma

Start Date: 11 Mar 81	Est Comp Date: Sep 81
Principal Investigator Gerald A. Merrill, CPT, MSC	Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation	Associate Investigators: James H. Anderson, Jr., M.D., MAJ, MC
Key Words: Degradation Endogenous opiates Plasma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $9,191	Periodic Review Results: Continue

Objective: To provide a rapid and inexpensive method to [illegible] prevent enzymatic degradation of endogenous opiates (Methionine, enkephalin, Leucine enkephalin, and β endorphin) to permit radioimmunological measurement [illegible] in plasma.

Technical Approach: Known quantities of ^{125}I labeled endogenous opiates (Met enkephalin, Leucine enkephalin, and Bendorphin) were added to aliquots of whole blood made endogenous opiate poor by incubation at 37°C for two hours. The blood was either treated with NaF (6mg/ml) or 1 N HCl with [illegible] leupeptin (100 µl/900 µl) + enkephalin extracted by MeOH via C-18 Seppak chromatography. Total activity recovered was assessed for each procedure [illegible] effect of each procedure on the degradation enzymes was determined [illegible] of activity binding of the labeled enkephalins.

Progress: Since submitting the protocol, refinements in the acid extraction [illegible] include MeOH elution from a C-18 Seppak column of the enkephalins greatly increased recovery of enkephalin from plasma. Therefore the [illegible] NaF was assessed in terms of the modified procedure.

NaF tended to increase the plasma fraction of blood recovered compared to EDTA therefore diluting the ^{125}I activity/unit plasma. However, total activity recovered in the plasma phase by each procedure was not significantly different (75-78%). In excess of 90% of the activity was eluted by MeOH from the C-18 Seppak. Slightly higher percentage of remaining activity was [illegible] in the extracted samples by antibody as compared to the NaF, probably because non-enkephalin entities were eliminated in the extraction

C-16-81 (continued)

process. In this lab no increase in recovery by using NaF could be demonstrated compared to the refined acid extraction procedure. Although ease of use of NaF is an advantage, the ability to concentrate the enkephalins by drying the MeOH and redissolving the opiates in the proper assay buffer is of greater advantage. The further investigation of the use of NaF to prevent enkephalin degradation is therefore not waranted.

No publications are anticipated from this project although results will be incorporated into publications from related protocols.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-53-81	Status: Ongoing

TITLE:

The Use of Monoclonal Antibody to a Pseudomonas Ribosomal Protein Antigen for Passive Immunization Against P. aeruginosa.

Start Date: [illegible] Aug 81		Est Comp Date: Aug 83
Principal Investigator Michael N. Lieberman, Ph.D., CPT, MSC		Facility Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation		Associate Investigators: Eleanor Ayala, DAC
Key Words: Monoclonal antibody Pseudomonas Ribosomal protein antigen		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $84	Periodic Review Results:

Objective: To determine whether monoclonal antibody to a Pseudomonas ribosomal protein antigen can protect mice by passive immunization against challenge with P. aeruginosa.

Technical Approach: Mice are immunized with the Pseudomonas ribosomal vaccine, and spleens are excised and spleen cell suspensions prepared. Spleen cells and myeloma cells (obtained from another laboratory where they are maintained in culture) are mixed in the presence of polyethylene glycol, resulting in a fusion of the two cell types. The fused cells, called hybridomas, are then fluorescein labeled with conjugated antigen. Next, the hybridoma cells are processed by the fluorescence activated cell sorter and plated such that individual cells are deposited in separate wells of tissue culture plates and grown in culture for several weeks. The hybridoma clones produced are then tested for antibody production to a particular antigen. Antibody positive hybridomas are subcultured and injected into the peritoneal cavity of mice. Ascites fluid is then collected from the mice and should contain relatively large amounts of monoclonal antibody. All monoclonal antibody preparations will be tested for antibodies to both protein and LPS antigens and those preparations showing antibody activity to protein antigen only will be tested for passive mouse protection. Preparation of Pseudomonas ribosomal vaccines and passive mouse protection experiments will be performed as previously described (C-7-77).

Progress: This protocol has just been initiated.

Detail Summary Sheet

Date: Proj No: C-28-73 Status: Completed

TITLE: The Simultaneous Determination of Instantaneous Aortic Flow, High Fidelity Intracardiac Pressures, Intracardiac Phonocardiography, Echocardiographic Dimensions and Derived Indices in Man.

Start Date: 6 Mar 73	Est Comp Date: Dec 80
Principal Investigator	Facility
Joseph P. Murgo, M.D., COL, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Medicine/Cardiology	William Craig, M.D., MAJ, MC
Key Words:	Julio Bird, M.D., MAJ, MC
Instantaneous aortic flow	N. Westerhof, Ph.D.
Cardiac catheterization	A. Pasipoularides, M.D., Ph.D.
Intracardiac phonocardiography	Bernard Kubal, Ph.D.

Accumulative MEDCASE Cost: $364,730.54	Est Accumulative OMA Cost: $15,984	Periodic Review Results:

Objectives:

1. To develop new techniques in cardiac catheterization, especially in the area of multi-solid state sensor catheters including high fidelity pressure sensors and electromagnetic flow meters. To utilize high speed biplane angiography and external echocardiography in conjunction with such techniques.

2. To utilize these techniques to define sophisticated parameters of ventricular function in patients with various cardiac diseases.

3. To develop specialized computer-assisted analyses of the data derived from such studies.

4. To quantitate left ventricular hydraulic output power.

5. To measure aortic and pulmonary artery input impedance by Fourier analysis and determine the effect of changing physiologic states upon the impedance.

Technical Approach: All adult patients for routine right and left heart catheterization are evaluated in the usual manner by a cardiac fellow prior to catheterization. The evaluation includes strip chart echocardiography to determine patient's suitability for certain aspects of the protocol. During catheterization special, custom-designed, right and left heart catheters are introduced into the right and left heart such that simultaneous high fidelity pressures are recorded from the pulmonary artery, right ventricle, right atrium, left ventricle, and aorta. In addition, electromagnetically derived aortic and pulmonary flow velocities are recorded from the same sites that high fidelity pulmonary artery and aortic pressures are obtained. Patients are studied during rest, supine exercise, and depending upon the patient's disease during a variety of physical stresses or pharmacologic interventions. Some patients also undergo simultaneous external echocardiography during catheterization. The study is terminated after bi-plane ventricular angiography and coronary arteriography if indicated.

Progress: Significant progress during FY 1981 resulted in publications in press including: aortic input impedance in normal man and left ventricular

(continued)

ejection dynamics in patients with hypertrophic and congestive cardiomyopathies. Currently work is in progress to evaluate the fluid dynamic changes responsible for subvalvular gradients in patients with aortic stenosis. Concurrently data analysis continues in ten patients from whom pulmonary artery impedance spectra were obtained in a high-fidelity micromanometry. It is anticipated that software development for computer-assisted data analysis will commence in the near future and will be carried out under new protocols as they are approved.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-9-75	Status: Ongoing

TITLE:

Clinical Outpatient Algorithm Validation - A Pilot Study.

Start Date: 30 Sep 74		Est Comp Date: Dec 81
Principal Investigator Barry W. Wolcott, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Emergency Medicine		Associate Investigators: Richard M. Tompkins, M.D.
Key Words: Algorithm Validation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine if clinical outpatient algorithms originally used to treat civilian outpatient populations can be validated and improved in a military outpatient environment.

Technical Approach: Collecting standard data bases on selected, defined outpatient populations presenting for evaluation of acute symptoms and then doing studies of their outcomes. Data base items linked to good/poor outcomes identified by statistical analysis.

Progress: Project will be completed in December 1981. Following completion, we will write a report defining an algorithm-directed acute care system which could be used within or without the Army Medical Department

Detail Summary Sheet

Date: 15 Jun 81 | Proj No: C-23-76 | Status: Completed

TITLE:
Demonstration of a Testosterone Binding Protein in Semen.

Start Date: 25 Feb 76	Est Comp Date: Sep 81
Principal Investigator Albert M. Thomason, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Endocrinology	Associate Investigators:
Key Words: Testosterone binding protein Electrophoresis	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost: $68	Periodic Review Results:

Objective: To demonstrate a testosterone binding protein in se...

Technical Approach: Electrophoresis of testosterone-labeled semen on polyacrylamide gels and isolation of the labeled band.

Progress: No specific testosterone binding substance could be isolated by the technique used.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-6-77	Status: Ongoing

TITLE.

Mechanism of Modulation of Lymphocyte Responses by Complement.

Start Date: 15 Sep 76		Est Comp Date: Jul 82
Principal Investigator Michel N. Laham, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Allergy-Immunology		Associate Investigators: David G. Burleson, Ph.D., MAJ, MSC Fatima Ebrahim, SSG
Key Words: Complement Cell mediated immunity		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $4,476	Periodic Review Results: Continue

Objectives: To determine whether the cleavage of complement component C2 by activated C1 and C4 takes place in the fluid phase.

To determine whether generation of breakdown products of C2 correlates with the modulatory effect on lymphocytes.

To investigate the effect of intact vs cleaved C2 on the generation of suppressor T cells.

Progress: Purified human C1, C4 and C2 are sequentially added to a suspension of peripheral blood lymphocytes in complement fixation buffer in a ratio of 1 : 15. Aliquots of the supernatants are withdrawn at 10, 20, 40 and 60 minutes, and kept frozen at -70°C until they can be assayed for residual C2 activity. At each time interval stated, the lymphocytes are sedimented, washed free of complement fixation buffer and resuspended in RPMI 1640 to be assayed for the proliferative responses to mitogens and the ability to suppress normal cells.

Progress: The main obstacle to the successful completion of this study has been our inability to obtain fresh EAC14 cells. As a result, we have not been able to measure residual C2 hemolytic activity. We are renewing our efforts to coordinate the shipment of cells so that we may obtain them within 24-48 hours of their shipment.

Project Summary Sheet

Proj No: C-23-77 Status: Ongoing

...ed by Longwave UV Light ... Psoriasis in th...

	Est Comp Date: Indefinite
	Facility Brooke Army Medical Center
	Associate Investigators: Charles W. Lewis, M.D., ... Richard M. Storm, M.D., ...
...(UVA)	
Est Accumulated ...	Periodic
...A Cost:	Review Date: Continuing

...efficacy of 8-methoxypsoralen ... (PUVA) in the treatment of psoria...

...s are given a prescribed dosage of ... prior to long-wave ultraviolet light exposure. ... to the skin is gradually increased to obtain ... disease and to promote pigmentation. ... protected by special ultraviolet glasses ... violet. The light dosage is carefully regulated to ... of the skin. All patients receive initial ... ophthalmologic evaluation and ... as well as ...

...ort, four new patients have entered the study and ... treated. One patient had palmoplantar psoriasis, ... type psoriasis, three patients had parapsoriasis ... patient had pustular psoriasis of Von ... The patient ... psoriasis received one treatment before developing fatal bac... sepsis and therapy failure. The three patients with parapsoriasis en... the patient with palmoplantar psoriasis had greater than 95% ... of their lesions. Two of the patients with plaque type psoriasis ... 90% clearing, while other patients with plaque type psoria... ... discontinuing treatment.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-1-78	Status: Ongoing

TITLE:

Tetracycline-induced Ultraviolet Fluorescence of Pathologic Pulmonary Tissues as Viewed Through the Fiberoptic Bronchoscope.

Start Date: Oct 77	Est Comp Date: Oct 81
Principal Investigator Joseph Matthews, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Pulmonary	Associate Investigators: John R. Holcomb, M.D., MAJ, MC
Key Words: Fluorescence Tetracycline-induced Fiberoptic Bronchoscope	

Accumulative MEDCASE Cost: $6407.00	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To establish whether in vivo tetracycline labeling can be used to aid the endoscopist in locating pathologic pulmonary tissues when viewed through a fiberoptic bronchoscope incorporating an ultraviolet light source.

Technical Approach: Antimicrobials of the tetracyclihne family are known to exhibit a characteristic fluorescence under ultraviolet light. It is also known that tetracycline will concentrate in abnormal tissues such as tumor. For this reason, it has been theorized and subsequently shown that patients given tetracycline can have an induction of a bright yellow fluorescence which can be seen under ultraviolet light in various tumor tissues. It is therefore proposed that patients who are suspected of having lung cancer who will undergo fiberoptic bronchoscopy be treated with tetracycline 250 mg q.i.d. for four days. At the time of fiberoptic bronchoscopy, if tumor tissue is seen, it would be biopsied, and no further procedures done. However, if no abnormal tissue is seen under routine fiberoptic bronchoscopy, then the patient would be examined with an ultraviolet light source. At that time, if an area of abnormal fluorescence is seen, a biopsy would be done in the routine fashion. Patients to be studied would include all patients who have consented to have the procedure performed, who would otherwise have an indication for fiberoptic bronchoscopy, i.e., patients with suspected lung tumors.

Progress: Due to personnel shortages and technical difficulties, no progress has been made on this protocol.

Detail Summary Sheet

Date: [illegible] 81	Proj No: C-9-79	Status: Terminated

TITLE:

Evaluation of Antidiar, Lomotil and Placebo in Acute Diarrheas

Start Date: 6 Feb 79		Est Comp Date:
Principal Investigator Leonard Duran, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Gastroenterology		Associate Investigators: Ernest L. Sutton, M.D., LTC, MC Dwayne Bohman, M.D., MAJ, MC
Key Words: Acute diarrhea Antidiar Lomotil Placebo		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To evaluate the effectivenss of AntidiarR, an over the counter drug; of LomotilR, a prescription drug approved as effective adjunctive therapy; and of a placebo in the treatment of acute diarrhea.

Methodical Approach: Patients age 18-65 presenting to the Brooke Army Medical Center Troop Clinic, Emergency Room and Acute Minor Illness Clinic with symptoms compatible with a diagnosis of acute diarrhea, will be considered for the study. The diarrhea must have begun less than 48 hours before enrollment in the study, and the patient must have experienced at least three watery, liquid or loose bowel movements within the previous twenty-four hours. Eligible participants will be assigned to one of three groups. Group 1 will receive Antidiar, Group 2 will receive Lomotil, and Group 3 will receive the Antidiar placebo.

Progress: The study was terminated by the drug company. 80 cases were completed. The drug company had recommended we study 320 cases in order that we might have meaningful statistics.

Detail Summary Sheet

Date: 30 Sep 81	Proj No: C-13-79	Status: Completed

TITLE:

Headache and Back Pain Clinical Algorithm Validation, Cost Analysis and AMOSIST Reliability.

Start Date: 22 Mar		Est Comp Date:
Principal Investigator Robert D. Slay, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Emergency Medicine		Associate Investigators: N. Joe Thompson, M.D., LTC, MC
Key Words: Algorithm AMOSIST		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine if new clinical algorithms, used to evaluate and treat patients presenting with acute headache and back pain, utilized by physician extenders, can be validated as effective in an outpatient population.

To compare the process of outcome data obtained by AMOSISTs and Internists (utilizing the same standard data base) in the evaluation and treatment of adults with headache or back pain.

To utilize the process of outcome data generated by the AMOSISTs and Internists to generate new clinical algorithms of measurable cost and outcome.

Clinical Approach: Data were collected by medical corpsmen in the walk-in clinic and emergency room using a common checklis. The itemson the checklist were chosen, based on an extensive literature review, to detect serious or portenailly serious conditions causing headaches and to discriminate between tension and migraine headaches.

Four weeks after each encounter, research assistants reviewed each patient's record and contacted the patient by telephone to determine the status of the illness. An internist who was not involved in the patient's care used the checklist, follow-up, and the other data in the medical record to assign a diagnosis.

Progress: Seven hundred twenty six patients presented with acute headaches which were diagnosed as tension (38%), migraine (25%), no diagnosis (30%) and other (6%). No patient had a life-threatening diagnosis. Although the internist making diagnoses had access to a great deal of information in addition to the initial clinical data for each patient, a simple rule based on 3-7 of the initial findings could duplicate his diagnostic decision with at least 80% accuracy.

Detail Summary Sheet

Date: 8 Oct 81	Proj No: C-14-79	Status: Terminated

TITLE:

Immunoglobulin Regulation in Rheumatic Disease.

Start Date: Mar 79		Est Comp Date:
Principal Investigator Gordon Walley, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Rheumatology		Associate Investigators: I. Jon Russell, M.D.
Key Words: Rheumatic disease Immunoglobulin regulation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To further characterize the physicochemical properties of amplifier factor in patients with systemic lupus erythematosus, rheumatoid arthritis dermatopolymyositis, progressive systemic sclerosis, Sjogren's syndrome and sarcoidosis, and to study the cellular interactions responsible for its function.

Technical Approach: This is a collaborative study with Dr. I. Jon Russell, University of Texas Health Science Center at San Antonio.

Blood samples will be obtained from normal control volunteers and from patients with a variety of connective tissue diseases including systemic lupus erythematosus, rheumatoid arthritis, dermatopolymyositis, progressive systemic sclerosis, Sjogren's syndrome and sarcoidosis for evaluation as outlined in the study protocol.

Progress: To date, no patients from BAMC have been entered on this study; therefore, the study is terminated.

Detail Summary Sheet

Date: 6 Oct 81	Proj No: C-34-79	Status: Completed

TITLE:

Triple Corticoid Integrated System (TCIS) 0.015% Cream Compared to 0.5% Hydrocortisone Cream in Treating Lichen Planus.

Start Date: 9 Aug 79		Est Comp Date:
Principal Investigator Charles W. Lewis, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology		Associate Investigators: J.R. Cook, M.D., MAJ, MC
Key Words: Lichen planus		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy of TCIS cream (0.015%) in lichen planus without occlusion.

To compare the efficacy of TCIS cream (0.015%) against 0.5% hydrocortisone in the same vehicle in treating lichen planus.

Technical Approach: The two test agents were applied to opposite sides of the body in the same area, in patients with symmetrical lichen planus, e.g. both forearms, both thighs, etc. Responses were evaluated and graded at two and four weeks. The study was double-blinded.

Progress: A total of 13 patients was studied at BAMC. Nine responded better to TCIS cream; two responded better to 0.05% hydrocortisone; two responded equally. In cooperation with others, a total of 51 patients were studied nationally. Overall results were similar to ours, indicating significantly better response of lichen planus to TCIS cream.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: C-35-79	Status: Terminated

TITLE:

Maintenance of Patency of the Ductus Arteriosus in Neonates with Cyanotic Congenital Heart Disease

Start Date: Aug 79		Est Comp Date:
Principal Investigator Kenneth R. Bloom, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology		Associate Investigators: Joseph P. Murgo, M.D., COL, MC
Key Words: Patent ductus arteriosus Cyanotic congenital heart disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To maintain an adequately patent ductus arteriosus in neonates who have cardiac malformations such that their immediate survival is dependent on blood flow through this channel. This will be done by infusion of Prostaglandin E_1 until diagnostic studies are completed and surgery carried out.

Technical Approach: Newborn infants presenting to the neonatal intensive care unit at BAMC and who have cyanotic congenital heart disease form this study group. Prostaglandin is infused through an umbilical artery catheter placed at the level of the ductus or, in some conditions, intravenously. Effects of the prostaglandin infusion are assessed by peripheral PO_2 measurement and, when applicable, by blood pressure measurements in the leg.

Progress: The study is terminated due to the projected departure of the principal investigator.

Detail Summary Sheet

Date: 23 Sep 81	Proj No: C-37-79	Status: Ongoing

TITLE:

Ankle Trauma Study.

Start Date: Sep 79		Est Comp Date: Sep 82
Principal Investigator N. Joe Thompson, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Emergency Medicine		Associate Investigators: Barry W. Wolcott, M.D., LTC, MC Robert Highley, M.D. James Bushyhead, M.D. Robert Wood, M.D.
Key Words: Trauma Algorithm		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To define predictors for the clinical diagnosis of ankle fracture, ligament rupture and strain; to develop cost efficient scheme for x-ray utilization in diagnosis of ankle trauma; to evaluate effects of different treatment modalities; to elucidate natural history of ankle trauma; to construct a family of algorithms with cost efficiency ratios; to determine best protocol for optimal care in ankle trauma.

Technical Approach: Each patient with indirect ankle trauma is offered the opportunity to enter the study. A PGY-2 in Emergency Medicine follows a precise format for obtaining a history and performing a physical exam which includes both plain and stress x-rays. The x-rays are then interpreted by the physician and assigned to a specific classification established by the study protocol. A previously established therpeutic modality is randomized. The patient is treated according to the established classification of the ankle injury and the randomized therapeutic modality. Follow-up at 48 hours and 90 days is done, depending upon the injury classification.

Progress: 666 patients have been entered on the study; however 900 are needed to complete the study. A final report will be submitted upon completion.

Detail Summary Sheet

Date: 13 Oct 81	Proj No: C-5-80	Status: Ongoing

TITLE:

Lopressor Intervention Trial.

Start Date: Jan 80		Est Comp Date: Sep 82
Principal Investigator Francis R. D'Silva, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology		Associate Investigators: Joseph P. Murgo, M.D., COL, MC
Key Words: Myocardial infarction Lopressor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of Metoprolol (LopressorR) in reducing the incidence of overall and cardiac death in survivors of recent myocardial infarction.

Technical Approach: Patients satisfying multiple criteria are enrolled within two weeks of acute myocardial infarction and given either placebo or metoprolol (Lopressor) 200 mg/day and followed on medication for one year. Metoprolol or placebo are administered in a randomized, double-blind fashion prospectively.

Progress: A total of 19 patients has been enrolled. Three have dropped out because of noncompliance. One patient has expired. Since the study is double blind, no results are available.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-6-80	Status: Ongoing

TITLE:

Clotting Studies in Liver Disease.

Start Date: 24 Jan 80		Est Comp Date: Jan 82
Principal Investigator Charles T. Thornsvard, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine		Associate Investigators: John F. Schultheiss, M.D., LTC, MC Thomas F. O'Meara, M.D., MAJ, MC
Key Words: Prothrombin time Vitamin K		Barbara Reeb, DAC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: Attempt to predict whether patients with prolonged prothrombin times with liver disease will or will not respond to Vitamin K administration.

Technical Approach: Patients who are to get Vitamin K will be given 10 mg. intramuscularly every 12 hours for the first 2 days. Serial prothrombin times will be recorded at 12 hour intervals for the first three days. An Echis carinatus time will be performed as a companion to the prothrombin time determination. The data will be analyzed retrospectively to determine whether Echis carinatus adequately predicted those patients who would respond or did respond to Vitamin K administration.

Progress: To date insufficient patients have been entered on this study in order to perform any meaningful evaluation. If patient accrual is not accelerated during the next year, this study will be terminated.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-7-80	Status: Ongoing

TITLE:

Evaluation of the Coagulation and Fibrinolytic Systems in Patients Undergoing Prostatectomy.

Start Date: 24 Jan 80	Est Comp Date: Sep 82
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology	Associate Investigators: Gary Wikert, M.D., CPT, MC John J. Posch, Jr., DAC
Key Words: Prostatectomy Coagulation system Fibrinolytic system	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $6,541	Periodic Review Results: Continue

Objectives: To conduct a detailed and prospective study of both the coagulation and fibrinolytic systems in patients undergoing either transurethral prostatectomy (TURP) or open prostatectomy.

To familiarize the hematology laboratory personnel with the use of chromogenic substrates for the measurement of components of both the coagulation and fibrinolytic systems.

Technical Approach: All tests reviewed in the original protocol have been standardized and are currently being performed by our laboratory. The Hematology Lab personnel have gained experience in the utilization of these assay methods and accurate data are being recorded on all tests.

Progress: Fifty patients have been registered on this study with 20 controls. Patient accrual has been completed and the only remaining part of this project is the completion of the laboratory analysis of the control patients with the statistical analysis of data. We plan to present this project in abstract form at the Tri-Service Urology Meeting.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-10-80	Status: Terminated

TITLE:

The Value of Immunotherapy with Dermatophagoides Mite Extract in the Treatment of House Dust Allergy.

Start Date: 3 Mar 80		Est Comp Date:
Principal Investigator Daniel A. Ramirez, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Allergy-Immunology		Associate Investigators:
Key Words: Immunotherapy Dermatophagoides mite extract House dust allergy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To asses the value of immunotherapy with Dermatophagoides mite extract in the treatment of house dust allergy.

Technical Approach: This study was to be a double-blind study using mite extract in immunotherapy from patients with clinical housedust sensitivity.

Progress: This study has been terminated. Our assumption for this study was that mites are an important allergen to housedust and that mites should therefore be present in housedust samples. It is now clear, however, that in San Antonio (and probably throughout the southwest), most homes do not contain dermatophagoides mites, most likely because the relative humidity is too low for their survival. No patients were enrolled into the study.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-17-80	Status: Ongoing

TITLE:

Role of Digoxin in Preventing Myocardial Toxicity in Cancer Patients Receiving Adriamycin.

Start Date: 6 Jun 80		Est Comp Date: Jun 82
Principal Investigator Walter H. Harvey, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Kenneth R. Bloom, M.D., LTC, MC J. Dean McCracken, M.D., COL, MC
Key Words: Digoxin Myocardial toxicity Adriamycin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine whether digoxin, administered prior to and during Adriamycin-containing chemotherapy regimens, reduces the incidence and extent of myocardial toxicity in cancer patients.

Technical Approach: Cancer patients to be treated with Adriamycin will be alternately assigned to one of two groups: (a) digoxin-treated, or (b) control. In order to assure equitable distribution of patients by age, sex and tumor type, participating medical oncologists will be aware of and adjust patient assignments as necessary. Participating cardiologists will be unaware of which patients are receiving digoxin and, therefore, all echocardiographic results will be interpreted by "blind" observers.

Digitalization of the digoxin-treated group will consist of the administration of 1.5 gm digoxin PO in divided doses for two days. Serum digoxin levels will be obtained from digoxin-treated patients prior to starting Adriamycin and before each echocardiogram.

All patients will undergo routine echocardiographic evaluation by m-mode technique, a method commonly used to evaluate cardiac function in patients on Adriamycin.

Progress: Approximately 7-10 patients are still needed on the Digoxin treated arm to complete this study. Patient accession has been slow secondary to patient early removal from study for progressive disease and patients being treated at facilities (other than BAMC) without echocardiography capabilities.

Detail Summary Sheet

Date: 14 October 1981	Proj No: C-23-80	Status: Ongoing

TITLE:

An Evaluation of Local Anesthetic Skin Testing and Progressive Challenge in Patients with a History of an Adverse Reaction to Local Anesthetics

Start Date: 24 Jun 80		Est Comp Date: FY 82
Principal Investigator Daniel A. Ramirez, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Allergy-Immunology		Associate Investigators:
Key Words: Local anesthetic skin testing Challenge Adverse reaction		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To confirm the safety and usefulness of this approach in a larger number of patients with histories of previous suspected adverse reactions to local anesthetics.

Technical Approach: Patients with history of adverse reactions to local anesthetics are being entered into this study, and evaluated with skin testing and progressive challenge. The challenge reaches 2 cc of S.C. 1% lidocaine.

Progress: Approximately 10 patients have been studied at BAMC. No adverse reactions have occurred with challenge. These patients are being entered into a larger multicenter study at Fitzsimons Army Medical Center.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-24-80	Status: Ongoing

TITLE:
Establishment of a Plasma Bank for Oncology Patients.

Start Date: 30 Jun 80		Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology-Oncology		Associate Investigators: Glenda Sutton, R.N., CPT, ANC John M. Rembold, CPT, MSC John J. Posch, Jr., DAC
Key Words: Plasma Banck Oncology patient		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $353	Periodic Review Results: Continue

Objective: To collect and freeze plasma samples from patients with cancer.

Technical Approach: Collection of blood specimens has been proceeding smoothly in the Oncology Chemotherapy Clinic. Specimens are collected in this location and immediately centrifuged, and the plasma collected. It is temporarily frozen in the refrigerator in the Oncology Clinic and then transported the same day to the -70° freezers in the Department of Clinical Investigation.

Progress: Approximately 100 patients have been registered on this study with their specimens being collected and frozen.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-35-80	Status: Completed

TITLE:

Double-blind Parallel Comparison of Sulconazole Nitrate 1% Solution and Clotrimazole 1% Solution in the Treatment of Tinea Cruris.

Start Date: 1 Jul 80	Est Comp Date:
Principal Investigator Charles W. Lewis, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators: Eric W. Kraus, M.D., MAJ, MC
Key Words: Tinea Cruris Sulconazole nitrate Clotrimazole	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the safety and efficacy of sulconazole nitrate 1% solution in the once-a-day, three-week treatment of tinea cruris in adult men and women as compared to 1% clotrimazole solution.

Technical Approach: Sulconazole or Clotrimazole was applied once daily to skin lesions. KOH and fungus culture was done initially and at 2, 3 and 7 weeks. Medication was stopped at end of 3 weeks, and 4 weeks later the patient was re-evaluated for relapse.

Progress: Twenty-four patients entered the study and 22 patients completed. Twelve patients were treated with Sulconazole, and 10 patients were treated with Clotrimazole. All 22 patients cleared by the end of three weeks. There was no significant difference between the two medications.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-36-80	Status: Ongoing

TITLE:

Double-blind Parallel Comparison of Sulconazole Nitrate 1% Solution and Placebo Solution in the Treatment of Tinea Versicolor.

Start Date: 1 Jul 80		Est Comp Date: Jul 82
Principal Investigator Charles W. Lewis, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology		Associate Investigators: Eric W. Kraus, M.D., MAJ, MC
Key Words: Tinea versicolor Placebo Sulconazole Nitrate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the safety and efficacy of sulconazole nitrate 1% solution in the once-a-day, three-week treatment of tinea versicolor in adult men and women as compared to placebo solution.

Technical Approach: This was a double blind study of Sulconazole Nitrate solution versus placebo applied to tinea versicolor lesions once daily for three weeks. KOH and Wood's lamp examination at two weeks and three weeks. If KOH was negative at three weeks, treatment was stopped and patient re-evaluated four weeks later.

Progress: Twenty-three patients completed the study. Twelve patients treated with placebo showed no evidence of clearing. Fungus was demonstrated by KOH. Elevent patients treated with Sulconazole Nitrate cleared completely, and KOH was negative by three weeks. It was concluded that Sulconazole Nitrate was superior to placebo in treatment of tinea versicolor.

At the request of the drug company, an additional 36 patients will be studied on this protocol.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-37-80	Status: Ongoing

TITLE:

Assessment of Granulocyte Function and Serum Opsonic Capacity in Nephrology Patients Undergoing Dialysis.

Start Date: 28 Jul 80		Est Comp Date: Jul 82
Principal Investigator Lucius F. Wright, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Nephrology		Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC
Key Words: Dialysis Polymorphonuclear leukocyte Redox metabolism Chemilumigenic probes		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2,143	Periodic Review Results:

Objectives: To assess granulocyte function in nephrology patients undergoing dialysis.

To assess serum opsonic capacity in these patients.

To investigate the relationship between dialysis associated activation of complement and the neutropenia observed during the initial phase of dialysis.

To assess peritoneal macrophage function in patients undergoing peritoneal dialysis.

Technical Approach: Blood samples are obtained from the arterial and venous tubings of patients undergoing routine hemodialysis. These samples are then taken to the laboratory where white cell counts and differentials are obtained and samples of the white cells are assessed for their opsonic capacity using several different molecular probes. Serum samples from each experiment are frozen and saved for batch analysis of complement components including molecular fragments.

Progress: Twelve patients have been studied in detail using a variety of different methodologies. From the basis of the data developed thus far, six patients will be restudied with analysis using a standard methodology which should permit tighter grouping of the mean data.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-41-80	Status: Terminated

TITLE:

The Effect of Nutrition on the Humoral-Phagocytic Axis.

Start Date: 26 Aug 80		Est Comp Date:
Principal Investigator Steven Cohen, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology-Oncology		Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC Richard A. Shildt, M.D., LTC, MC
Key Words: Humoral-phagocyte axis Chemiluminescence Nutritional repletion		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To evaluate the microbicidal activity of the humoral-phagocytic axis of host immune defense using chemiluminescence techniques in malnourished patients.

To evaluate the effect that nutritional repletion has on serum opsonic capacity and on polymorphonuclear leukocyte function as measured by chemiluminescence.

Technical Approach: Fifteen to twenty patients judged to be malnourished as defined by the parameters listed in the protocol were to be studied. After hyperalimentation, the changes in chemiluminescence with changes in nutritional status were to be correlated.

Progress: The principal investigator decided not to initiate the study.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: C-42-80	Status: Terminated

TITLE:

Solumedrol for the Treatment of Acute Myocardial Infarction

Start Date: 9 Sep 80		Est Comp Date:
Principal Investigator Francis R. D'Silva, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology		Associate Investigators: Joseph P. Murgo, M.D., COL, MC
Key Words: Myocardial Infarction Solumedrol		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the efficacy of two pharmacologic IV doses of Solumedrol in reducing the mortality and morbidity associated with acute myocardial infarction.

Technical Approach: Study terminated.

Progress: The study was terminated because of a conflict of interest since the principal investigator has taken over the study C-5-80, Lopressor Intervention Trial.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-1-81	Status: Completed

TITLE:
Hemoserine Inhibition of Sickling as Viewed by Electron Microscopy

Start Date: 7 Oct 80		Est Comp Date:
Principal Investigator Georges C. Benjamin, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Internal Medicine		Associate Investigators: Lucia Olalde, DAC Steven K. Koester, DAC
Key Words: Hemoserine inhibition Sickling Electron microscopy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $20	Periodic Review Results:

Objective: To evaluate the effect of hemoserine on polymerization of hemoglobin S in the intact erythrocyte.

Technical Approach: Whole blood was obtained by venipuncture in EDTA. After fixing with Karnovsky's fixative, smears of each sample was viewed by light microscopy.

Progress: One patient was available for study. At 0.1 M concentrations, hemoserine did not inhibit sickling in the two assays performed. EM of the sickled cells showed filament formation in the deoxygenated treated and untreated cells. The oxygenated controls were too hemolyzed to study.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-2-81	Status: Ongoing

TITLE:

Evaluation of the Coagulation, Fibrinolytic, and Humoral Immune Abnormalities Induced by Crotalus Atrox (Western Diamond Back Rattlesnake) Snakebite

Start Date: 10 Oct 80		Est Comp Date: Sep 82
Principal Investigator John J. Posch, DAC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Robert C. Allen, M.D., Ph.D., MAJ, MC Thomas G. Glass, Jr., M.D.
Key Words: Snakebite Envenomated Rattlesnake		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $5,664	Periodic Review Results: Continue

Objectives: To evaluate and characterize the coagulation, fibrinolytic and humoral immune abnormalities induced in patients envenomated by Crotalus atrox (western diamondback rattlesnake).

Technical Approach: Coagulation tests as outlined in the protocol are being performed on snakebite patients. Serum and plasma specimens are stored at -70°C for further evaluation to include chemiluminescence technique for the evaluation of opsonic function and complement activity. Venoms collected from C. atrox specimens of different sizes were preliminarily tested for possible differences in coagulant vs fibrinolytic activity. Significant differences were noted and venoms were subsequently obtained from three different size ranges of snakes. Thrombin-like activities and fibrinolytic activities were evaluated on all individual venoms. Further characterization of the procoagulant and fibrinolytic processes involved is being performed using plasma and fibrinogen coagulation procedures.

Progress: Specimens from 24 snakebite victims have been collected and stored in frozen aliquots. Twelve of these patients were serially collected on subsequent days. Approximately one-half of the total amount of coagulation procedures to be performed on these are completed. Chemiluminescence procedures will be performed when all specimens are received. Although coagulation abnormalities and clinical bleeding problems have been observed in several of these patients, final conclusions are pending completion of tests and rest of patient group.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-3-81	Status: Ongoing

TITLE:

Study of Granulocyte Function in Leukemia Patients Receiving Granulocyte Transfusions

Start Date: 10 Oct 81		Est Comp Date: Sep 82
Principal Investigator Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army medical Center
Dept/Sec: Department of Medicine/Hematology		Associate Investigators: Donald C. Townsend, M.D., MAJ, MC
Key Words: Granulocyte function Leukemia Granulocyte transfusion		Robert C. Allen, M.D., Ph.D., MAJ, MC Terry E. Pick, M.D., LTC, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: Prospective evaluation of neutrophil function and humoral immunity in patients with leukemia.

Evaluation of changes induced in humoral immunity and neutrophil function by either radiation therapy or chemotherapy.

Evaluation of kinetics of transfused neutrophils in leukemia patients.

Correlation of improvement in neutrophil function and humoral immunity in recipients of granulocyte transfusions and clinical course.

Technical Approach: Baseline evaluation of the patient's humoral opsonic capacity will be performed. Granulocyte redox function will also be studied. Additional studies will be performed with routine CBCs during the induction phase of chemotherapy. Once a patient has entered remission of his leukemia, a repeat study will be performed on a monthly basis. Serum opsonic capacity and granulocyte redox function will be assayed by the micro technique of probe amplified chemiluminescence.

Progress: Only one patient to date has been studied. This is secondary to low patient accrual with no patients needing granulocyte transfusion in the last 10 months at Brooke. If sufficient patients cannot be accrued to this study over the next year, it will be terminated.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-5-81	Status: Ongoing

TITLE:

The Natural History of Patients with Large Local Reactions (LLR) Following a Hymenoptera Sting

Start Date: 3 Feb 81		Est Comp Date: Sep 83
Principal Investigator Daniel A. Ramirez, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Allergy-Immunology		Associate Investigators:
Key Words: Hymenoptera sting Large local reactions (LLR)		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To study the natural history of patients who have experienced LLR following an insect sting. Several aspects of this problem will be studied: a. What is the risk of systemic anaphylaxis in this group of patients? and b. Can patients with histories of LLR and at risk of anaphylaxis be identified prospectively.

Technical Approach: Patients who meet the above objectives will undergo the following:

a. Venom skin testing - up to 1 ug/ml of concentration.

b. Obtain specific venom IgE and IgG.

c. Stay challenged under controlled conditions to assess current reactivity.

d. Obtain specific venom IgE and IgG's following sting challenge.

Progress: Eight patients with positive skin tests to venom have been entered into the study. None of these patients have consented to in-hospital study. The plan for these patients is to follow-up on field stings when it occurs.

Detail Summary Sheet

Date: 9 Nov 81	Proj No: C-8-81	Status: Ongoing

TITLE:

Comparative Evaluation of Methods of Surveillance for Nosocomial Infections

Start Date: 3 Feb 81	Est Comp Date: Sep 82
Principal Investigator C. Kenneth McAllister, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Infectious Disease	Associate Investigators: John L. Carpenter, M.D., LTC, MC
Key Words: Nosocomial infection	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To study several different methods by which Infection Control personnel might search for nosocomial infections, as well as the method presently employed at Brooke Army Medical Center (BAMC), in order to define clearly a system which would most efficiently achieve the goals of surveillance for nosocomial infections.

Technical Approach: Data for this study will be collected on McBee Keysort cards. A card will be initiated for each patient whose chart is actually reviewed by a member of the Infection Control Surveillance Team. Charts will be selected for review on the basis of the presence of one or more of the nine screening clues (positive culture, fever, antibiotic therapy, a verbal report, presence on an ICU, isolation precautions, hospital stay of 21 days or more, and leukemia) disclosed during survey activities. During the chart review, the presence of additional factors associated with NI will be noted on the "Also Present" column. A determination as to whether or not a NI is present will be made. As appropriate, the site will be indicated. Follow-up on the patient will be noted simply by initiating a new keysort card for each review of the chart with entries being confied to the small section devoted to follow-ups.

Progress: Initial review of the data is inconclusive. Further study is indicated.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-9-81	Status: Ongoing

TITLE:
Thyroid Function in Cancer

Start Date: Feb 81		Est Comp Date: Jun 82
Principal Investigator Lawrence Pupa, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Internal Medicine		Associate Investigators:
Key Words: Thyroid Cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To definte the state of thyroid function in seriously ill oncology patients.

Technical Approach: Ten patients will be studied. Blood will be drawn and T_3U, FTI, T_4, TSH, T_3RIA, and RT_3 will be measured. Patients on thyroid hormone or with a family history of thyroid disease will be excluded.

Progress: Seven patients have been studied thus far and thyroid function results are pending.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-10-81	Status: Ongoing

TITLE:

Evaluation of the Complement System and Humoral Immunity in Patients Undergoing Fibrinolytic Therapy.

Start Date: 3 Feb 81		Est Comp Date: Jun 82
Principal Investigator David Dooley, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Robert C. Allen, M.D., Ph.D., MAJ, MC
Key Words: Complement system Humoral immunity Fibrinolytic therapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To conduct a prospective evaluation of the effects of fibrinolytic therapy on the complement and humoral immune systems.

Technical Approach: No deviation from the ascribed technical approach as listed in the protocol have been performed.

Progress: Three patients have been studied. Complete evaluation and analysis of data will be pending further patient accrual. It is anticipated this study will accrue adequate numbers of patients during the next fiscal year.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-12-81	Status: Ongoing

TITLE:

Study of Granulocyte Function, Complement Activity and Coagulation in Patients with the Adult Respiratory Distress Syndrome (ARDS)

Start Date: 4 Feb 81		Est Comp Date: Jun 82
Principal Investigator Nathan Erteschik, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Internal Medicine		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Robert C. Allen, M.D., Ph.D., MAJ, MC David Glendenning, M.D., LTC, MC
Key Words: ARDS Complement granulocyte-induced endothelial damage		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: Evaluation of neutrophil metabolism by chemiluminescence in patients with ARDS.

Measurement of complement activity via the classical and alternate pathways in patients with ARDS.

Study of the coagulation and fibrinolytic systems in patients with ARDS.

Correlation of steroid therapy with the above objectives in patients with ARDS.

Technical Approach: Arterial and mixed-venous blood samples are collected from patients with both arterial and Swan-Ganz catheter lines in place. Samples are collected for: WBC metabolism and complement activity using chemiluminescence; CBC; Pt, PTT; Fibrinogen, FSP, TT, Plasminogen and plasminogen activators, pre-kallikrein and kallikrein inhibitors, HMWK. These are performed on plasma prepared from anticoagulated whole blood with Na citrate, centrifuged and stored at -70°C.

Progress: Three categories of patients: 1) ARDS, with 2 patients; 2) cardiac catheterization group, with 7 patients, 3) other patients with both catheter lines in place but without ARDS, with 10 patients. Coagulation studies are still stored, and waiting to be completed on patients already in the study.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: C-17-81	Status: Ongoing

TITLE:

Effect of DMSO on Human Squamous Cell Cultures

Start Date: 11 Mar 81		Est Comp Date: Jul 83
Principal Investigator Walter C. Anderson, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology		Associate Investigators: Michel N. Laham, M.D., LTC, MC
Key Words: Human squamous cell cultulres DMSO		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: Using in vitro human squamous carcinoma cell lines (SCLO 16), we will determine whether DMSO induces their differentiation into more mature epithelial cells.

Technical Approach: Squamous cell cultures will be perpetuated in vitro by periodic transfer into fresh monolayers in RPMI 1640. Once an in vitro cell line is established, the effect of DMSO will be determined by adding serial dilutions of DMSO to individual monolayer cultures. After varying intervals from 10-60 minutes, the cells will be washed free of DMSO and incubated in fresh RPMI 1640 at 37°C and 5% CO_2. After 24-48 hours of incubation, the individual monolayers will be fixed and stained using H&E and the degree of differentiation determined by light microscopy.

Progress: So far, considerable difficulty has been encountered in establishing the cells line due to bacterial killing.

Detail Summary Sheet

Date: 10 Jun 81	Proj No: C-19-81	Status: Transferred

TITLE:

The Prevalence of Antibiotic Tolerant Staphylococcus Aureus in Nasal Cultures of Different Adult Population Groups

Start Date: 11 Mar 81		Est Comp Date:
Principal Investigator Frank J. Baker, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Infectious Disease		Associate Investigators:
Key Words: Staphylococcus aureus		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To perform an epidemiological survey of Staphylococcus aureus tolerance from isolates not causing clinical infection and determine prevalence rates in different adult population groups.

Technical Approach: This study was not started.

Progress: The study was transferred to William Beaumont Army Medical Center.

Detail Summary Sheet

Date: 14 Oct 81	Proj No: C-24-81	Status: Ongoing

TITLE:

Identification of Bacterial Receptors on the Intestinal Mucosa of Rabbits and Determination of Its Role in the Pathogenesis of Bacterial Diarrhea

Start Date: 1 Apr 81		Est Comp Date: Jun 82
Principal Investigator Robert A. Berendson, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Gastroenterology		Associate Investigators: John F. Schultheiss, M.D., LTC, MC C. P. Cheney, Ph.D., CPT, MSC
Key Words: Bacterial receptors Bacterial diarrhea		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $632	Periodic Review Results: Continue

Objectives: Isolate segments of small intestine from adult rabbits and compare the adherence ability of RDEC-1 and several control E. coli strains to these intestinal segments.

Indirectly examine the various segments of intestine to determine if there are any differences in the carbohydrate content between receptor positive and receptor negative intestinal segments.

Determine the role the host receptors for RDEC-1 located on the intestinal mucosa by orally challenging receptor positive and receptor negative rabbits.

Technical Approach: Four adult female New Zealand white rabbits will be mated with designated male rabbits, and their litters allowed to be maintained as naturally as possible by the mother. On days 18, 21, 24, 28, and 35, infant rabbits from each litter will be sacrificed and segments of rabbit small intestine will be frozen rapidly in isopentane. Frozen intestinal tissue will be sectioned in a cryostat and an attempt will be made to identify the specific sugar units which may constitute the receptor for RDEC-1 and E. coli which has specific adherence to rabbit small bowel. For this, the tissue will be exposed to different lectins, which are sugar specific proteins, in an attempt to blodk adherence of RDEC-1 over the sectioned tissue after exposure to the lectins. An indirect immunophorescent technique will be used to identify RDEC-1 adherence.

Progress: The first group of female rabbits was mated in early July. The first two litters were born in mid-August. In the last six weeks, we have sacrificed the rabbits following the schedule outlined above. The frozen tissue is being kept in the Department of Clinical Investigation. At the present time, some of the lectins have not been received, and we are waiting for these so we can go into the second part of the experiment.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-25-81	Status: Ongoing

TITLE:

Single-Dose Treatment of Urinary Tract Infections in Women

Start Date: 1 Apr 81	Est Comp Date: Sep 82
Principal Investigator C. Kenneth McAllister, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Infectious Disease	Associate Investigators: AMOSIST personnel
Key Words: Urinary Tract Infection	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To investigate the efficacy and safety of treating women with uncomplicated UTI's of the lower urinary tract with a single dose antibiotic.

To demonstrate a cost savings to the US Army by utilizing a single dose of antibiotic therapy for UTI vs 10-14 days of convential therapy.

To provide a convenient means of treating UTI which optimizes patient compliance and follow-up.

Technical Approach: Twenty-six women entered into the study. Study design such that only adult women ages 18-55 with symptoms/signs compatible with cystitis are given 3.0 grams amoxycillin single dose therapy (SDT). SDT patients receive urine culture plus gram stain prior to therapy; and at 5 to 9 days, then the final culture at 4 weeks post treatment.

Progress: Results thus far are 90% curative at initial follow-up. No conclusions have been drawn at this point other than efficacy and safety has been confirmed.

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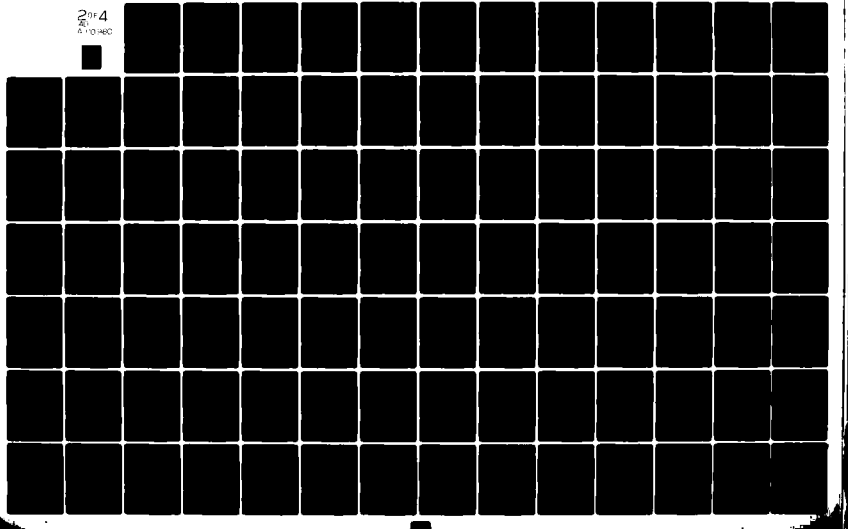

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-26-81	Status: Ongoing

TITLE:

The Effect of Sterile Gloves on the Incidence of Contamination and Infection of Intravenous Catheters

Start Date: 1 Apr 81	Est Comp Date: Sep 82
Principal Investigator Charles E. Davis, Jr., M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Infectious Disease	Associate Investigators: John L. Carpenter, M.D., LTC, MC
Key Words: Intravenous catheters Infection Contamination	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $434	Periodic Review Results: Continue

Objective: To study the effect of the use of sterile globes during the insertion of intravenous catheters on the incidence of infection of indwelling intravenous catheters and sepsis secondary to intravenous catheter infection.

Technical Approach: Participants will be divided into two groups. Group 1 will have the IV inserted by one of the investigators with the added precaution of wearing of sterile gloves. Group 2 will have the catheter inserted in a similar manner but without sterile gloves. Skin cultures will be taken before and after placement of the IV.

The following variables will be analyzed: Relation of technique of insertion to (1) incidence of pre and post-insertion postive skin cultures, (2) incidence of positive catheter culture and time to occurrence, (3) incidence of phlebitis and time to occurrence and (4) incidence of catheter being the source of bacteremia to occurrence.

Progress: Due to a change in principal investigators, no progress has been made.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-27-81	Status: Ongoing

TITLE:

Karyology of in vitro Cultured Basal Cell Epithelioma Tissue.

Start Date: 1 Apr 81		Est Comp Date: Unknown
Principal Investigator Stuart J. Salasche, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology		Associate Investigators:
Key Words: Karyology Basal Cell Epithelioma Cell culture		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $123	Periodic Review Results: Continue

Objective: To investigate chromosomal abnormalities in basal cell epithelioma cells and to initiate a cell culture line for this and further studies.

Technical Approach: Part of the tissue specimen taken for biopsy for basal cell carcinoma is taken to the lab and pure BCC islands devoid of fibrous stroma are torn out, chopped up and placed in cell culture media and then incubated.

Progress: Progress has been virtually nil due to several problems, most notably the cell culture lines becoming infected and discarded within 48 hours. Antibiotics added to media so fat has not helped.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-28-81	Status: Ongoing

TITLE:

In vitro Synthesis of Immunoglobulins and Suppressor Cell Activity in Patients with Solid Tumors and Lymphomas on and off Therapy

Start Date: 1 Apr 81	Est Comp Date: Jun 82
Principal Investigator Michel N. Laham, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Allergy-Immunology	Associate Investigators: David G. Burleson, Ph.D., MAJ, MSC Richard A. Shildt, M.D., LTC, MC Charles M. Loyd, SFC
Key Words: Suppressor cell activity Lymphoma Immunoglobulins	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $165	Periodic Review Results: Continue

Objective: To evaluate the in vitro synthesis of immunoglobulins in patients with different types of tumors.

To determine whether suppressor T-cell activity is increased in patients with lymphoma as compared with solid tumor patients.

To assess the effect of chemotherapy on immunoglobulin synthesis and suppressor cell activity in both groups of patients.

Technical Approach: 20 cc of blood are obtained from each patient by venipuncture. Peripheral blood lymphocytes are isolated by sedimentation on Ficoll-Hypaque. The cells are assayed for their proliferative responses to mitogens and their ability to synthesize immunoglobulins by a reverse hemolytic plaque assay. Mixed lymphocyte cultures are also carried out to determine the cells ability to suppress proliferation and antibody synthesis by normal lymphocytes.

Progress: Forty-eight patients have been studied so far in nine separate experiments. Twelve of the patients were studied before and after chemotherapy. There were no significant differences in proliferative responses or antibody synthesis. However, there appears to be decreased suppression of normal cells after therapy.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-29-81	Status: Ongoing

TITLE:

Treatment of Severe Erythema Multiforme with Systemic Steroids

Start Date: 3 Apr 81		Est Comp Date: Unknown
Principal Investigator Charles W. Lewis, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology		Associate Investigators: Nancy D'Silva, M.D., CPT, MC Eric W. Kraus, M.D., MAJ, MC
Key Words: Erythema multiforme Steroids		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine if Prednisone is effective in the treatment of severe erythema multiforme.

Technical Approach: A 3-4 mm punch biopsy or an excisional biopsy for H and E will be performed as confirmation of the clinical diagnosis. Direct immunofluorescence will be performed on the biopsy specimen in an effort to demonstrate immune deposit if present. Involved areas will be photographed upon entrance into the study. Follow-up photographs will be taken at 1, 3 7, and 15 days after institution of prednisone of placebo therapy.

Progress: So far we have not received any appropriate patients for the study.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-31-81	Status: Ongoing

TITLE:
Profile of Aortic Impedance in Patients with Congestive Cardiomyopathy

Start Date: 11 May 81		Est Comp Date: May 82
Principal Investigator Joseph P. Murgo, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology		Associate Investigators: N. Westerhoff, Ph.D. B. J. Rubal, Ph.D.
Key Words: Aortic impedance Congestive cardiomyopathy Cardiac catheterization		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate the role of afterload reduction and exercise on the aortic impedance profile of patients with congestive cardiomyopathy.

Technical Approach: Patients admitted to this study have undergone elective cardiac catheterization to evaluate the possibility of surgically correctable problems and to assess the hemodynamic response to afterload reduction by nitroprusside and exercise. Routine left and right heart catheterizations were performed. High-fidelity multisensor pressure velocity catheters were employed to obtain simultaneous aortic pressure and flow-velocity information. This data was stored on electromagnetic tape and submitted to a computer for Fourier analysis following the catheterization procedures. Standard hemodynamic parameters were evaluated and the aortic input impedance spectra plotted.

Progress: To date, data have been obtained from ten patients with congestive cardiomyopathy. Work continues in data analysis and a preliminary statistical analysis has been performed. Nipride increased cardiac output and reduced left ventricular end-diastolic pressure. No significant change in heart rate was found. Exercise resulted in an increase in heart rate, slight change in cardiac output and significantly increased pulmonary capillary pressure.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-33-81	Status: Ongoing

TITLE:
Renal Function in Primary Hyperparathyroidism

Start Date: 12 May 81		Est Comp Date: May 83
Principal Investigator Lucius F. Wright, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Nephrology		Associate Investigators: Charles J. Foulks, M.D., MAJ, MC
Key Words: Hyperparathyroidism Renal function		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To gather detailed information about renal function in patients with primary hyperparathyroidism at the time of diagnosis, and to follow these functions serially in patients not undergoing surgery. These data should permit a more precise estimate of the risk of "medical" therapy versus "surgical" therapy in patients with mild, asymptomatic, primary hyperparathyroidism.

Technical Approach: Patients entered into this study are being admitted to the hospital for 5-days of metabolic balance studies and renal function tests which include the ability to concentrate and dilute the urine. Response to ammonium chloride loading and bicarbonate administration, calcium excretion and assorted data on endocrine function including parathyroid hormone assays are also being obtained at the same time.

Progress: To date seven patients have been entered and completed the first phase of the study and are now being followed in the Renal Clinic. Three more patients have been identified who are suitable for entrance into the study and will be studied when facilities are available.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-34-81	Status: Ongoing

TITLE:

The Effect of Propranolol on Cardiac Ejection Fractions as Determined by Gated Scans in Thyrotoxic Patients

Start Date: 15 Jun 81		Est Comp Date: Jun 83
Principal Investigator Thomas J. Taylor, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Endocrinology		Associate Investigators: Robert J. Telepak, M.D., LTC, MC Roswell Beck, M.D., LTC, MC
Key Words: Propranolol Thyrotoxic Cardiac ejection		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To study the effects of Propranolol on cardiac ejection fractions in thyrotoxic patients and thereby critically assess the relative merits of this mode of therapy.

Technical Approach: MUGA studies are being done on Grave's patients at 0 and 3 hours pre- and post-institution of Propranolol therapy 60 mg. p.o. Six patients have had MUGA studies. The decrease in dv/dt and ejection fraction has been consistent except in one case where the second MUGA was done at 2 hours.

Progress: We do not have a severely ill patient to draw a conclusion. But, in normals, a mild decrease in ejection fraction occurs at 3 hours.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-35-81	Status: Ongoing

TITLE:

Hepat : Artery Embolization in the Management of Primary or Metastatic Hepatic Neoplasm

Start Date: 15 Jun 81		Est Comp Date: Jun 83
Principal Investigator Walter H. Harvey, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: J. Dean McCracken, M.D., COL, MC
Key Words: Hepatic artery embolization Nepatic neoplasm		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate of hepatic embolization of primary or metastatic neoplasia in liver.

To evaluate the morbidity of hepatic embolization.

To evaluate the response rates of patients undergoing embolization with metastatic disease to liver to a historical control group.

Technical Approach: Hepatic artery embolization using Ivalon^{R} particles for peripheral embolization and steel coils for proximal embolization was utilized in the management of patients with hepatic neoplasm. Nine patients with regionally confined disease in the liver and who had failed either hepatic artery infusion or systemic chemotherapy were eligible. Embolization was carried out through a percutaneous femoral approach. Hepatic artery placement was verified by angiography

Progress: Six patients with colon cancer and one patient each with hepatoma, squamous cell carcinoma and uterine leiomyosarcoma make up the study group. Seven patients are still alive with two patients deceased. No deaths were attributable to the embolization procedure. Median follow-up time is 3 months. The longest follow-up is eight months with the patient alive and with stable disease in the liver. Although this study is limited by the short follow-up period and few numbers of patients, hepatic artery embolization may be useful in the management of regionally confined hepatic neoplasm.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-36-81	Status: Ongoing

TITLE: Comparison of Gray-Scale Ultrasonography and Computed Tomography with Infusion Nephrotomogram in Early Diagnosis of Adult-type Polycystic Kidney Disease

Start Date: 15 Jun 81		Est Comp Date: Jun 83
Principal Investigator Lucius F. Wright, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Nephrology		Associate Investigators: Harold Cable, M.D., CPT, MC
Key Words: Polycystic kidney disease Gray-scale ultrasonography Computed tomography Nephrotomogram		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To compare Gray-scale ultrasonography and abdominal computed tomography to infusion nephrotomography in establishing the diagnosis of adult-type polycystic kidney disease in asymptomatic persons at risk.

Technical Approach: Children of patients known to have polycystic kidney disease who agree to be screened will have infusion nephrotomography, Gray-Scale ultrasonography and abdominal CT scan with and without contrast enhancement to assess them for the presence of polycystic kidney disease. The patients who are to be studied have a 50% risk of having inherited the disease from their infected parent. These studies will be reviewed all at one time after they are obtained by investigators who are blinded to the results of the other studies.

Progress: Thus far, four subjects have been entered into the study, and approximately fifteen others have been identified who are likely to qualify for admission.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-37-81	Status: Ongoing

TITLE:

Evaluation of Curettage and Electrodesiccation in Treatment of Human Basal Cell Epitheliomas

Start Date: 15 Jun 81		Est Comp Date: Jun 82
Principal Investigator Stuart J. Salasche, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology		Associate Investigators:
Key Words: Basal cell epithelioma Curettage Electrodesiccation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To assess the adequacy of curettage and electrodesiccation as a method of treatment for basal cell epitheliomas of the skin in a prospective study.

Technical Approach: Patients with small, previously untreated basal cell carcinoma were treated in the standard fashion with electrodesiccation and curretage. After completion of the procedure a small surgical saucerized excision was taken 1 mm around and under the defect and subjected to frozen section inspection in order to determine if any tumor cells remained. If tumor cells were identified, further tissue was taken until a tumor free plane was attained.

Progress: Fifty study cases have been completed thus far with residual tumor islands found in 12 cases (24%). The majority of these positive cases were from lesions on the nose and in the nasolabial fold. Since the anticipated overall cure rate with this procedure is claimed to be 95% for these small, primary BCE, we feel our findings are very significant and plan to continue the study to statistically significant numbers.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-38-81	Status: Ongoing

TITLE:

The Use of Mannitol and Lasix in Intractable Ascites

Start Date: 15 Jun 81		Est Comp Date: Jun 82
Principal Investigator Willie R. Whitaker, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Internal Medicine		Associate Investigators: Lucius F. Wright, M.D., MAJ, MC
Key Words: Intractable ascites Mannitol Lasix		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To compare Thiazide to a combination of Mannitol plus Lasix in maintaining urine output and mobilizing intractable ascites in patients with cirrhosis.

Technical Approach: Patients admitted to the Gastroenterology Service with ascites that fails to respond to bed rest and sodium restriction are eligible for diuretic therapy with either Thiazide or Mannitol and Lasix. The choice of treatment is determined randomly and after three days to assess response a crossover phase is provided.

Progress: This is a new study and thus far no patients have been entered.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-39-81	Status: Ongoing

TITLE:

Program on the Surgical Control of the Hyperlipidemias

Start Date: 15 Jun 81		Est Comp Date: Jun 86
Principal Investigator Ronald R. Blanck, COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine		Associate Investigators:
Key Words: Hyperlipidemias Myocardial infarcion Atherosclerosis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To follow atherosclerotic plaque progression in coronary arteries in patients following myocardial infarction who have been randomized into a control group and a group that has experienced marked cholesterol reduction by modified intestinal bypass. By extension, this is a test of the hypothesis that altering lipid levels significantly alters atherosclosis.

Technical Approach: Data is being collected from clinical record cover sheets and patients contacted for possible inclusion in the study.

Progress: So far, none of the actual study has been carried out at Brooke Army Medical Center, though it is anticipated this will occur next fiscal year.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-42-81	Status: Ongoing

TITLE: Effects of Dietary Sodium and Potassium Intake upon the Response of the Conscious Dog to Acute Hyperkalemia: The Quantitative Role of the Liver

Start Date: 15 Jun 81	Est Comp Date: 84
Principal Investigator Charles J. Foulks, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Nephrology	Associate Investigators: Lucius F. Wright, M.D., MAJ, MC
Key Words: Hyperkalemia	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To study the quantitative role of the liver in the homeostasis response of a conscious dog to acute hyperkalemia.

Technical Approach: The approach used involves quantitatively time integrated response of serum potassium to infusion of potassium under a variety of metabolic circumstances. In an effort to develop data on the quantitative role in the liver and maintenance of internal homeostasis and procetion against acute hyperkalemia, cannulas will be plased to permit sampling of the portal and hepatic vein. The technical approach has not varied from that described in the original clinical investigation protocol.

Progress: This project will be initiated once the clinical inestigation animal facility is available.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-51-81	Status: Completed

TITLE:

Effect of Histamine Antagonists on Parathormone and Serum Calcium Levels in a Patient with Hypoparathyroidism

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator James K. Gilman, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Internal Medicine		Associate Investigators:
Key Words: Histamine antagonists Parathormone Hypoparathyroidism		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine if H_1 and H_2 receptor blockade singly or in combination cause a reduction in serum concentrations of parathormone and ionized calcium in a patient with hypoparathyroidism.

Technical Approach: A patient with hypoparathyroidism was placed on a metabolic diet off all diuretics, calcium, and vitamin D supplements. Once serum calcium stabilized, the patient was started on thiazide diuretic and salt-restricted diet in an attempt to raise serum calcium levels (Porter et al NEJM 298:11577, 1978). Patient still required supplemental calcium and vitamin despite these measures. He was then challenged with cimetidine for three days which failed to produce any decline in serum.

Progress: Patient's serum calcium was 7.0-7.2 mg% at the initiation of the study. With the restriction of sodium intake and administration of thiazide diuretics, serum calcium declined even further to less than 6.0 mg%. Electrocardiogram showed $Q\text{-}T_c$ prolongation and patient had positive Trousseau's sign at this point in his course. On hospital day nine, 1.25-dihydroxy Vitamin D was started along with calcium supplements. Serum calcium increased over a period of several days to about 8.0 mg% and remained stable at that despite subsequent challenge with cimetidine. Joint challenge with H_1 receptor blockers (hydroxyzine) and H_2 receptor blockers (cimetidine) were not performed due to fact patient had already spent three weeks in the hospital.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-52-81	Status: Ongoing

TITLE:

Effect of Aspirin (ASA) on Airway Responses

Start Date: 7 Jul 81		Est Comp Date: Jul 82
Principal Investigator Daniel A. Ramirez, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Allergy-Immunology		Associate Investigators:
Key Words: Nonallergic rhinitis Aspirin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective; To investigate the effects of aspirin on airway responses in man. Specifically the following questions will be answered: a. What effect does ASA have on upper and lower airway resistance in patients with nonallergic rhinitis with eosinophilia (NARES)? and b. Are patients with NARES - or any identifiable subset thereof - at particular risk of developing lower airway obstruction from aspirin?

Technical Approach: Subjects are to be challenged with 10 grains of aspirin and their nasal airway resistance and pulmonary functions will be measured and followed.

Progress: Currently awaiting necessary MEDCASE items to be purchased to begin this project.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-54-81	Status: Ongoing

TITLE:

Phosphate Homeostasis in the Normal and Renal Failure Dogs

Start Date: 6 Aug 81		Est Comp Date: Unknown
Principal Investigator Lucius F. Wright, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Nephrology		Associate Investigators: Charles J. Foulks, M.D., MAJ, MC
Key Words: Homeostasis Renal failure		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To define the kinetics of phosphate elimination in response to a number of maneuvers in normal dogs and in dogs with experimentally induced reductions in renal failure. These data will be used to examine the hypothesis that secondary hyperparathyroidism develops in early renal failure as a consequence of the neet to amplify the renal excretory response to phosphate loading that occurs as an inevitable result of eating.

Technical Approach: This protocol is designed to test the feasibility of developing time integrated constants for serum phosphate and urine phosphate excretion in response to intravenous and oral phosphate loading in conscious dogs.

Progress: Implementation of this study awaits completion of the Clinical Investigation Laboratory Animal Facility.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-56-81	Status: Ongoing

TITLE:

Evaluation of Indomethacin as a Protective Agent Against Radiation-Induced Esophagitis

Start Date: 17 Aug 81		Est Comp Date: Aug 82
Principal Investigator Robert A. Berendson, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Gastroenterology		Associate Investigators: John F. Schultheiss, M.D., LTC, MC Gary West, M.D., COL, USAF, MC John R. Sharp, M.D., LTC, USAF, MC
Key Words: Esophagitis Rediation therapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine if the administration of Indomethacin to patients undergoing radiotherapy of the chest area will prevent the development of esophagitis

Technical Approach: Patients receiving radiation therapy for different mediastinal tumors in a port that will include radiation to the esophagus will be randomized blindly into four grous - one a group of controlled subjects and three groups which will receive three different dose levels of Indomethacin, an agent that has been demonstrated in animal studies to be protective for radiation-induced esophagitis. The patients will undergo, prior to radiation therapy, esophagoscopy with photographs, with biopsies and brushings being taken at this time. At the completion of radiotherapy, each patient will undergo a second endoscopy with biopsy, photography, and collection of serum specimens. The patients will be asked to report any difficulty with odynophagia or dysphagia at weekly intervals. The treatment group will be compared with the contorl goup and with each other using Student's Test and a one-way fixed effect model analysis of variance.

Progress: This is a new study. The placebo tablets have been obtained and, in the course of the next few weeks, we intend to go ahead with the coding of the placebo and the Indomethacin tablets. We expect to start including patients in the study in the near future.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-58-81	Status: Ongoing

TITLE:

The Specificity of the Priming on the Nasal Mucous Membranes by Allergens and the Effect of Pharmacological Intervention

Start Date: 20 Aug 81		Est Comp Date: Aug 83
Principal Investigator Daniel A. Ramirez, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Allergy-Immunology		Associate Investigators: Gwenesta Melton, M.D., CPT, MC
Key Words: Allergen Nasal mucous membranes		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To investigate further the phenoeman of mucous membrane priming by antigens. Several aspects of the problem will be studied: a. Does it occur in different aeroallergen systems? b. Is the priming effect on the nasal mucosa specific for the allergen that induces it? c. What is the effect, if any, of antihistamines, intranasal corticosteroids and cromolyn sodium on nasal priming? d. Is the priming effect due to an increase of specific IgE?

Technical Approach: Study subjects will be challenged intranasally to the appropriate allergens over successive days to prime their mucus. By challenging with a different allergen to which the patient is also resistive, we will determine if the phenomenon is specific or not. Also, antihistamines, corticosteroids and cromolyn sodium will be used prior to the study to determine whether priming can be pharmacologically inhibited. Specific IgE (by RAST) will then be obtained.

Progress: The equipment neceasary to perform nasal airway resistance measurements is not available. We are waiting for MEDCASE items to be purchased so this project can be started.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-59-81	Status: Ongoing

TITLE:
Utility of Urological Investigation of Females with Invasive Urinary Tract Infections

Start Date: 20 Aug 81		Est Comp Date: Aug 82
Principal Investigator John L. Carpenter, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Infectious Disease		Associate Investigators: C. Kenneth McAllister, M.D., LTC, MC
Key Words: Urinary tract infection Cystoscopy Intravenous pyelogram		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To investigate the sensitivity and specificity of intravenous pyelograms and cystoscopies in female patients who have failed single-dose treatmetn of urinary tract infections.

To determine the cost effectiveness of these urological investigations in this subset of patients with urinary tract infections.

Technical Approach: All patients who failed single dose amoxycillin therapy for urinary tract infections as per the protocol C-25-81 are entered onto the protocol. They undergo cystoscopy and intravenous pyelogram in order to determine the percent of such patients who have surgically correctible anatomic defects that contribute to urinary tract infections.

Progress: At the present time no patients have been entered onto this protocol.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-61-81	Status: Ongoing

TITLE:

A Phase IV Surveillance Study of Sucralfate in the Treatment of Duodenal Ulcer Disease - An Open Label Study

Start Date: 1 Sep 81		Est Comp Date: Jun 82
Principal Investigator John F. Schultheiss, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Gastroenterology		Associate Investigators: Robert A. Berendson, M.D., MAJ, MC Leonard Duran, M.D., CPT, MC Joseph W. Jackson, M.D., MAJ, MC USAF
Key Words: Duodenal ulcer disease Sucralfate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To observe the use of Sucralfate in a population of duodenal ulcer patients for effectiveness and to detect possible adverse reactions.

Technical Approach: Participants will be asked to take one Sucralfate tablet on an empty stomach one-half hour before meals three times a day and at bedtime. During the course of the study, participants will be asked to refrain from using aspirin, aspirin-containg drugs, and any analgesics they have been using to relieve ulcer symptoms. Treatment will terminate at the end of six weeks.

Progress: This is a new study.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-66-81	Status: Ongoing

TITLE: Double-Blind Parallel Comparison of Sulconazole Nitrate 1% Solution and Clotrimazole 1% Solution in the Treatment of Acute Symptomatic Tinea Pedis

Start Date: 24 Sep 81	Est Comp Date: Sep 82
Principal Investigator Charles W. Lewis, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators: Eric W. Kraus, M.D., MAJ, MC
Key Words: Tinea Pedis	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the safety and efficacy of sulconazole nitrate 1% solution in the treatment of acute symptomatic tinea pedis in adult men and women as compared to 1% clotrimazole solution.

Technical Approach: In this double-blind paralel comparison patients will be treated once a day for four weeks with 1% sulconazole or 1% clotrimazole solution. Patients will be examined on initiation of therapy, at two weeks, and on completion of four weeks of therapy. To determine relapse rate, patients who are KOH negative at four weeks will return for examination four weeks after the end of therapy.

Progress: This is a new study.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-67-81	Status: Ongoing

TITLE: Double-Blind Parallel Comparison of Sulconazole Nitrate 1% Cream and Miconazole Nitrate 2% Cream in the Treatment of Symptomatic Tinea Pedis

Start Date: 24 Sep 81		Est Comp Date: Sep 82
Principal Investigator Charles W. Lewis, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology		Associate Investigators: Eric W. Kraus, M.D., MAJ, MC
Key Words: Tinea Pedis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To compare the safety and efficacy of sulconazole nitrate 1% cream in the treatment of symptomatic tinea pedis in adult men and women as compared to that of miconazole nitrate 2% cream.

Technical Approach: Patients will be treated once a day for four weeks with either sulconazole or miconazole nitrate cream. The two drugs will be randomly assigned. Patients will be examined on initiation of therapy, at two weeks, and on completion of four weeks of therapy. Patients who are KOH negative after four weeks of therapy will be re-examined at eight weeks to determine the incidence of relapse.

Progress: This is a new study.

Detail Summary Sheet

Date: 9 Nov 81	Proj No: C-12-79	Status: Ongoing

TITLE:

Clinicopathologic Study of Uterine Vascular Changes with and without Hormonal Influence

Start Date: Mar 79		Est Comp Date: Sep 82
Principal Investigator Charles V. Wilson, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators: Milton H. Leman, M.D., COL, MC
Key Words: Uterine vascular changes Oral contraceptives		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To study the association of intimal thickening of uterine arteries with oral contraceptive use in women undergoing hysterectomy with and without cervical and uterine pathology.

Technical Approach: All patients undergoing hysterectomy by an abdominal or vaginal route are eligible for the study and will have their operation performed in the standard manner. The operative specimen will be taken directly by the pathologist for both electron microscopic and light microscopic fixation and preparation. Sections will be made of both uterine and myometrial vessels and examined for intimal thickening and other abnormal vascular changes. The patients will be divided into study groups for comparison as follows: Group I - no hormonal exposure; and Group II - hormonal exposure, 50-100 micrograms, for 1 year, 1-2 years, or 2 years or more.

Progress: This project was temporarily delayed due to inability to obtain pathological data. This situation has been rectified and patients are once again being enrolled on the study.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-15-80	Status: Completed

TITLE:

Fluorouracil Cream vs Podophyllum in the Management of Vulvar Condyloma Accuminatum

Start Date: 28 Mar 80		Est Comp Date:
Principal Investigator John E. Miers, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators: Milton H. Leman, M.D., COL, MC
Key Words: Vulvar condyloma accuminatum Fluorouracil cream Podophyllum		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine whether Fluorouracil cream is a better therapeutic agent with less side effects and toxicity than Podophyllum.

Technical Approach: Participants in the study were divided into two groups. To insure the groups were scientifically comparable, they were stratified based on the size and number of lesions. Group I was treated with 5% Fluorouracil cream for 5 days each week x 4 weeks. Group II received on application of podophyllum once each week x 4 weeks.

Progress: Sixteen patients were entered into the study. In Group II six patients were treated; three were stratified in the less than 1 cm group, and three were greater than 1 cm. In Group I three patients had lesions less than 1 cm and seven had lesions greater than 1 cm.

The overall average response was a response grade of 3.3 in 3 weeks for fluorouracil versus a response grade of 2.7 over 3.5 weeks for podophyllum. Though these numbers are still insufficient to be significant, the 5-FU appears to be more efficacious in the larger condyloma than podophyllum.

Detail Summary Sheet

Date: 20 Apr 81	Proj No: C-9-80	Status: Terminated

TITLE:

Identification of T-cell Leukemias-Lymphomas with Heterologous Antisera

Start Date: Jan 80		Est Comp Date:
Principal Investigator Lizardo Cerezo, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pathology		Associate Investigators: Isidoro Chapa, DAC
Key Words: T-cell lymphoid neoplasms Non-T leukemias-lymphomas		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $184	Periodic Review Results:

Objective: To use anti-human peripheral T-cell serum and anti-human brain serum (in addition to other currently established techniques) to distinguish T-cell lymphoid neoplasms from non-T leukemias-lymphomas in adult and pediatric patients. Pathologic diagnoses, initial extent of disease, age groups and remission rates will be compared between the two groups.

Technical Approach:

Progress: We have not been able to demonstrate the specificity of our rabbit sera for peripheral CLL B-cells or of our rabbit anti-human brain sera for T-cells.

In view of the fact that anti-T and anti-B antisera are now commercially available, the study is terminated.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: C-12-80	Status: Terminated

TITLE:

Cytochemistry of Epithelial Neoplasms

Start Date: 3 Mar 80		Est Comp Date:
Principal Investigator Lizardo Cerezo, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pathology		Associate Investigators:
Key Words: Epithelial neoplasms Cytochemistry		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To study multiple cytochemical parameters of epithelial neoplasms and thereby determine if cytochemical profiles may contribute to the accurate diagnosis of these tumors. The study would also evaluate the feasibility and reliability of cytochemistry of postmortem tissues.

Technical Approach: We will attempt to study 50 cases which will first be separated into diagnostic groups (based on light and electron microscopic interpretations). Within each group autopsy vs surgical specimens will be distinguished. In this fashion, within similar tumor groups, we will evaluate if major difference exists in staining reactions between biopsy and postmortem tissues and if certain reactions are characteristic for specific tumor types.

Progress: This study was terminated due to the release from active duty of the principal investigator.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-21-80	Status: Ongoing

TITLE:

In Vitro Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue.

Start Date: 7 May 1980		Est Comp Date: Jan 82
Principal Investigator Roby P. Joyce, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pathology		Associate Investigators:
Key Words: Demyelination Remyelination Central Nervous Tissue		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $805	Periodic Review Results: Continue

Objective: To establish at Brooke Army Medical Center the capability to study demyelination and remyelination of mammalian central nervous tissue in a reliable cell culture laboratory model.

Technical Approach: Minced newborn mouse cerebellum is cultured in Eagle's basic medium enriched with fetal calf serum and glucose at 35.5°C in a 5% CO_2 incubator. Twice weekly the cultures are washed and fed. Using an inverted tissue culture microscope and 35mm camera attachment, the growth and eventual decline of the colonies is documented.

Progress: Continuing efforts to establish a reliable mammalian central nervous system tissue culture laboratory model for the study of demyelination and remyelination have been frustrated by the lack of consistency of our results. Originally, the cultures were of excellent quality but recent attempts to culture the tissue have been associated with bacterial contamination and failure to grow. Steps being taken to correct these problems include media changes, the use of different incubation techniques, and re-evaluation of our technique (especially regarding sterility).

Detail Summary Sheet

Date: 20 Oct 81		Proj No: C-64-81	Status: Ongoing

TITLE:

Detection of Rotavirus in Selected Pediatric Patients Utilizing Rotazyme, Rotavirus Diagnostic Kit

Start Date: 23 Sep 81	Est Comp Date: Aug 82
Principal Investigator Thomas R. Perez, DAC	Facility Brooke Army Medical Center
Dept/Sec: Department of Pathology/Virology	Associate Investigators: S. Vern Juchau, M.D., LTC, MC James Higbee, Ph.D., MAJ, MSC George J. Kasai, Ph.D., Paula Mosman, DAC
Key Words: Rotavirus Rotazyme, Rotavirus Diagnostic Kit	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To field test the Rotazyme Kit as a possible new diagnostic procedure for detection of active rotavirus infections in pediatric gastroenteritis patients.

To provide a definitive rotavirus diagnosis allowing physicians to make a proper diagnosis and alert him to potential complications.

To potentially reduce the use of antimicrobial agents

To provide better patient management.

To determine BAMC area seasonal period for rotavirus infections.

Technical Approach: A stool sample will be submitted for rotavirus and bacterial culture. If a stool sample is impractical, a rectal swab may be submitted using a "Virocult" for rotavirus study and a bacterial "Culturette" for bacterial culture. The stool/rectal swab submitted will be processed by standard methods for detection of other possible viral agents. Specimens will also be analyzed using the Rotazyme, Rotavirus Diagnostic Kit.

Progress: This is a new study.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: C-6-81	Status: Completed

TITLE:

Assessment of Opsonic Capacity and Phagocytic Function in the Newborn Using Microliter Quantities of Whole Blood

Start Date: 3 Feb 81		Est Comp Date:
Principal Investigator Leonard E. Nagorski, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC
Key Words: Opsonic capacity Phagocytic function Newborn		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $270	Periodic Review Results:

Objective: To employ recently devised chemiluminescent techniques to investigate the humoral-phagocyte axis of immune defense in neonates. In particular:

A. Opsonic activity of neonate and maternal serum to different bacterial antigens.

B. Assessment of classical complement activity and also alternative complement activity in neonates with comparison to maternal and control adult serum.

C. Assessment of neonate polymorphonuclear leukocyte microbicidal metabolic responsiveness to immune and non-immune stimuli.

Technical Approach: Maternal bloods were collected by venipuncture with the routine laboratory blood specimens at the time of presentation in labor. Infant blood were collected from the ligated umbilical cord at delivery. At three days of age, blood is routinely obtained from the infant for PKU determination. Any additional drops of blood will be collected at this time and used for PMNL testing and where possible for measurement of opsonic capacity. At two weeks of age a repeat PKU is drawn by heel stick. Any additional drops of blood will be collected and assayed as described above.

Progress: The results indicate that maternal specific activity is high-normal using the luminol-opsonified zymosan technique. This view is consistent with the observation that myeloperoxidase activity is higher in pregnant females. The specific activity of newborn cord blood phagocytes was, however, significantly depressed relative to maternal or control specimens. The specific oxygenation responses using DBA-PMA were

C-6-81 (continued)

equivalent for control and maternal specimens; but once again, the newborn specimens were depressed as measured by this technique. The results support the conclusion that both myeloperoxidase and superoxide associated oxygenation by phagocytes in newborn whole blood are depressed at the time of birth.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-35-74	Status: Onging

TITLE:
Clinical Evaluation of Cisternography Utilizing ^{111}Indium DTPA.

Start Date: 25 Jan 74		Est Comp Date: Indefinite
Principal Investigator Robert J. Telepak, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology/Nuclear Medicine		Associate Investigators: Ronald K. McCauley, M.D., MAJ, MC
Key Words: Cisternography Hydrocephalus		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the safety and efficacy of 111Indium DTPA for cisternography.

Technical Approach: The isotope is introduced intrathecally. The patient is imaged at 6 and 24 hours after injection. Progress of the isotope is followed. Cotton plegets are placed in the nose and ears of patients suspected of CSF leaks. They are removed and counted at 6 and 24 hours.

Progress: Three patients have been scanned in the past year. The information provided by this procedure has been very valuable in documenting problems involving CSF.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-12-77	Status: Ongoing

TITLE:
Intravenous Administration of ^{131}I (NP 59) for Adrenal Evaluation of Imaging.

Start Date: 15 Nov 76	Est Comp Date: Not known
Principal Investigator Robert J. Telepak, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology/Nuclear Medicine	Associate Investigators: Roswell N. Beck, Jr., M.D., MAJ, MC Ronald K. McCaulety, M.D., MAJ, MC
Key Words: Adrenal scan, NP-59	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: The patient is injected I.V. with 1-2 millicuries of I-131 labeled NP 59. Scanning over the adrenal glands is performed at 3 days and again at approximately 7 days after injection. Visual image interpretation as well as computer enhanced processing of the images is used to evaluate them. In selected patients, two repeat studies employing dexamethasone suppression may also be performed.

Progress: During the past year, there was no usage of this product. The protocol is being maintained in an active status should a diagnostic need arise.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-22-78	Status: Terminated

TITLE:

Technetium-99m-pyridoxylideneglutamate (99m-Tc-PG) for Diagnosis of Hepatobiliary Disease

Start Date: Apr 77		Est Comp Date:
Principal Investigator Robert J. Telepak, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology/Nuclear Medicine		Associate Investigators: Roswell N. Beck, Jr., M.D., LTC, MC
Key Words: Biliary scan Hepatobiliary disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the clinical efficacy of Tc-99m-PG as a diagnostic hepatobiliary and gallbladder agent.

Technical Approach: The patient is injected with 15 millicuries of 99m technetium labeled pyridoxylideneglutamate (PYG) with images obtained every 5 minutes in the anterior projection. In normal persons, activity is promptly seen in the liver, and then concentrates in the biliary tree with visualization of the gallbladder usually by 30 minutes after injection and evidence of activity within the bowel shortly thereafter. The scan is most useful for evaluating acute cholecystitis in which the gallbladder is not visualized because of obstruction of the cystic duct. The scan is also useful for evaluating patency of the biliary tree into the bowel and also for evaluating surgical anastomoses and shunts involving the biliary tree.

Progress: During the past year four patients were scanned. Although the studies provided very useful diagnostic information, the protocol was terminated due to the availability of a new product (99mTc Diethyl-IDA) which provides information considerably more useful in diagnosing the integrity of the hepatobiliary system.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-22-80	Status: Completed

TITLE:

Correlation of Epidurography with Anatomical Investigation of the Lumbar Spinal Canal.

Start Date: 23 Jun 80	Est Comp Date: Jun 81
Principal Investigator Nadi S. Hibri, M.D.	Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology	Associate Investigators:
Key Words: Epidurography Herniated nucleus pulposus	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To gain a better understanding of the relationship of a herniated nucleus pulposus to the epidural and subarachnoid spaces.

Technical Approach: The spines are prepared at the time of autopsy in the following manner: a mixture of Knox gelatin, Renografin M-60 and acrylic paint is heated to approximately 80°C and then cooled to room temperature while stirring. The mixture is subsequently injected as a liquid into the epidural space, the vertebral bodies of L4 and L5 , and the subarachnoid space. The specimen is cooled after it is removed which allows the injected mixture to gel and harden. Then CT of the lumbar spine is performed. Finally, the specimen is frozen solid and ban-sawed in as nearly as possible the same plane as that used for the CT sections. The ban-sawed sections are then thawed and photographed in color.

Progress: Four cadavers were examined in which we demonstrated vividly the relationship of the epidural space to the rest of the spaces within the spinal cord. This new information helped us in appreciating abnormalities on epidurograms we performed on 35 patients with low back pain in whom the clinical findings or myelograms were equivocal.

Detail Summary Sheet

Date: 1 Oct 81	Proj No: C-20-81	Status: Ongoing

TITLE:

Technetium-99m-Diethyl-IDA for Diagnosis of Hepatobiliary and Gallbladder Pathology

Start Date: 18 Mar 81		Est Comp Date:
Principal Investigator Robert J. Telepak, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology/Nuclear Medicine		Associate Investigators: Roswell N. Beck, M.D., LTC, MC
Key Words: Hepatobiliary Scan		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the clinical efficacy of 99mTc-EHIDA as a hepatobiliary agent.

Technical Approach: Each patient is studied following a 4-6 hour period of fasting (when possible). Following IV injection of 7-15 mCi of Technetium 99m Diethyl-IDA, simultaneous computer acquisition is performed for further delay analysis. After nuclear images are stored, distribution curve data is derived. Initially, views will be obtained every 5 minutes post injection for the first 30-45 minutes. Additional views are obtained at one hour and 24 hours if obstruction is suspected. If the gallbladder does not visualize in 1-2 hours, acute, chronic cholecystitis or gallbladder dysfunction is suspected.

Progress: During the past year, 75 patients were scanned utilizing this procedure. The results have been remarkable and provided extensive diagnostic data. This procedure provides a safe, rapid, non-invasive evaluation of the hepatobiliary system. Information acquired on patients in many cases eliminates the need for more invasive studies.

Detail Summary Sheet

Date: 16 Oct 81	Proj No: C-21-81	Status: Ongoing

TITLE:

Evaluation of Young Amateur Boxers by Computed Tomography

Start Date: 26 Mar 81		Est Comp Date:
Principal Investigator Luis Canales, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology		Associate Investigators:
Key Words: Computed tomography		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To assess the extent of intracranial abnormalities that may develop in young amateur boxers.

Technical Approach: CT sccaning if done of amateur boxers (head) after a boxing bout.

Progress: Fifteen cases have been studied. No abnormalities were found. More are needed for meaningful conclusions.

Detail Summary Sheet

Date: 20 Oct 81	Proj No: C-65-81	Status: Ongoing

TITLE:

Odontodysplasia and the Trico-Dento-Osseous Syndrome, Type II

Start Date: 23 Sep 81		Est Comp Date: Sep 82
Principal Investigator Frank Quattromani, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology		Associate Investigators:
Key Words: Odontodysplasia Trico-Dento-Osseous Syndrome		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1,290	Periodic Review Results: Continue

Objective: The principal investigator has found odontodysplasia, tightly coiled hair and calvarial osteosclerosis and thickening in four generations of a family of German ancestry. A study of the entire family is proposed not only for genetic counseling purposes, but also to gain a better understanding of this disease so that it may be distinguished from other closely allied syndromes.

Technical Approach: To search for and identify appropriate blood group markers present in affected individuals as well as those not affected to determine whether there is association or linkage. Kindred known to have the TDO Type II association will be examined and a detailed genetic and historical study of the kindred will be performed.

Blood will be drawn for genetic association and linkage studies as well as total body roentgenographic examination to demonstrate osseous structures involved.

Progress: This is a new study.

Detail Summary Sheet

Date: 20 Oct 81	Proj No: C-21-78	Status: Ongoing

TITLE:

Clinical Study of Intraocular Lenses.

Start Date: Feb 78		Est Comp Date: Unknown
Principal Investigator John Gearhart, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Ophthalmology		Associate Investigators: Donald Griffith, M.D., COL, MC Charles Aronson, M.D., LTC, MC
Key Words: Intraocular lens Cataract extraction		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To establish the safety and effectiveness of this device for use in human subjects according to guidelines recommended by the Food and Drug Administration ophthalmic advisory panel.

Technical Approach: Data required for the study is collected and reported to the intraocular lens companies in the individual format required by each company. The data consists of ocular preoperative, operative, and postoperative information with particular emphasis on resulting vision and complications accompanying implantation of the intraocular lenses. The lens manufacturers then compile the data for the nationwide study and supply the FDA with the results.

Progress: In the past year several lens manufacturers have been released from the most detailed (core) investigations and now require only adjunct reporting of data and any adverse reactions.

Patients treated at BAMC have continued to show improved vision postoperatively.

Detail Summary Sheet

Date: 20 Oct 81	Proj No: C-14-80	Status: Ongoing

TITLE:

Abdominal Wound Closure

Start Date: Mar 80		Est Comp Date: Indefinite
Principal Investigator Michael J. Spebar, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/General Surgery		Associate Investigators: General Surgery Residents
Key Words: Running suture Interrupted suture Wound closure		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine if there is a difference in wound closures performed by interrupted or running suture techniques on the fascial layers.

Technical Approach: Wound closure techniques are evaluated for: (a) time of closure at operation and (b) immediate and long-term postoperative wound complications.

Progress: The project continues to evaluate wound closure techniques with special reference to the continuous, monofilament suture material and the interrupted wire suture technique.

Detail Summary Sheet

Date: 20 Oct 81	Proj No: C-20-80	Status: Terminated

TITLE:

Evaluation of St. Jude Prosthetic Heart Valve

Start Date: May 80		Est Comp Date:
Principal Investigator George F. Schuchmann, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Cardiothoracic		Associate Investigators:
Key Words: Prosthetic Heart Valve		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: Clinical evaluation of the St. Jude Medical bi-leaflet, center opening cardiac valve prosthesis.

Technical Approach:

Progress: Unfortunately, after going to the work of getting this protocol approved, the Company withdrew permission for us to implant St. Jude valves. This withdrawal of permission for use of this prosthesis was requested by FDA.

Detail Summary Sheet

Date: 20 Oct 81	Proj No: C-7-81	Status: Ongoing

TITLE:

Open-ended Cutaneous Vasostomy

Start Date: 3 Feb 81		Est Comp Date: Sep 82
Principal Investigator Rafael V. Mora, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Urology		Associate Investigators: Mauro P. Gangai, M.D.
Key Words: Spermatic granuloma Open-ended cutaneous vasostomy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To avoid the major complications, such as spermatic granuloma of the vas, epididymal discomfort and pain due to intravasal pressure buildup and spontaneous recanalization which often occur in patients who have a vasectomy performed in the conventional manner for surgical sterility.

Technical Approach: Under local anesthesia and through separate scrotal incisions, each vas is isolated, ligated distally with Weck clips, the distal end returned to the scrotum, the proximal (testicular end of each vas sptulated and anastomosed to the lower edge of the incision with 4-0 chromic catgut, as a stoma.

Progress: Seventy-eight patients that presented to the Urology Clinic for elective sterilization and followed for six months post vasectomy are the basis of this study. The patients were prospectively randomized into two groups: Group A - a total of 34 patients who underwent the open-ended cutaneous vasostomy and Group B - a total of 41 patients who underwent vasectomy by the conventional technique. The complications in each group were tabulated:

Group A (Open-ended vasostomy)		Group B (Ligature vasectomy)	
Persistent vascutaneous fistula	- 1	Symptomatic sperm granuloma	- 3
Spermatocele at skin level	- 1	Spermatocele	- 1
Epididymitis	- 3	Epididymitis	- 2
		Hematohydrocele	- 1

C-7-81 (continued)

The purpose of this study was to decrease the sequelae from conventional vasectomy using the open-ended technique. Inspite of having a higher percentage of epididymitis (9%) in Group "A", as opposed to 5% in Group "B", there were no patients with symptomatic sperm granuloma in Group "A" as opposed to 7.5% incidence of symptomatic sperm granuloma in Group "B".

Detail Summary Sheet

Date: 20 Oct 81	Proj No: C-18-81	Status: Terminated

TITLE:

Immunoglobulin A Levels in Blood and Nasal Secretions of Patients with Nasal Polyposis

Start Date: 11 Mar 81		Est Comp Date:
Principal Investigator Warner L. Bruner, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Otolaryngology		Associate Investigators:
Key Words: Immunoglobulin A Nasal polyposis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: A possible etiologic mechanism for nasal polyposis is sought by trying to identify a derangement in the immunologic status of patients with polyps.

Technical Approach:

Progress: Terminated due to technical difficulty with laboratory support and investigator's desire to approach problem from different aspect.

Detail Summary Sheet

Date: 20 Oct 81	Proj No: C-22-81	Status: Ongoing

TITLE:

The Effect of Prophylactic Antibiotics on Wound Sepsis Following Elective Cholecystectomy

Start Date: 26 Mar 81		Est Comp Date: Jun 82
Principal Investigator Greg A. Bowman, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/General Surgery		Associate Investigators: Michael J. Walters, M.D., LTC, MC
Key Words: Prophylactic antibiotics Cholecystectomy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine if the use of prophylactic, broad-spectrum antibiotics will significantly decrease the incidence of wound sepsis following elective cholecystectomy for chronic cholecystitis and/or cholelithiasis.

Technical Approach: Patients undergoing elective cholecystectomy will be randomized into control and study groups. The control group will receive no antibiotics. The study group will receive intravenous Cefamandole immediately prior to surgery and 6 and 12 hours after surgery. Cultures of bile for aerobes and anaerobes will be obtained intraoperatively. Patients will be followed postoperatively for signs and symptoms of wound sepsis.

Progress: To date, 13 patients have been enrolled in the study group and 7 patients have been enrolled in the control group. Neither group has experienced a wound infection.

Detail Summary Sheet

Date: 20 Oct 81	Proj No: C-23-81	Status: Ongoing

TITLE:

Comparative Efficacy of Serum Albumin Products

Start Date: 31 Mar 81		Est Comp Date: Mar 84
Principal Investigator Nelson E. Isenhower, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Anesthesiology		Associate Investigators: Chester E. Pruett, M.D., MAJ, MC
Key Words: Albumin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $35,280	Periodic Review Results:

Objective: To determine if there is a difference in the therapeutic effectiveness of the Federal Standard 25% Normal Serum Albumin U.S.P. (which requires refrigeration with 10 year shelf life) and the commercially available 25% Normal Serum Albumin U.S.P. (which requires no refrigeration with 3 year shelf life).

Technical Approach: A clinical trial evaluating the clinical response of patients to the commercially available 25% normal serum albumin, non-refrigerated, to the Federal standard 25% normal serum albumin USP. The indications for use of the volume expanders was left up to the treating physicians. The clinical results of the commercially available albumin is compared with the response in patients during the past three years.

Progress: The study is just getting underway. Initial impressions are there appears to be no difference in the two sources of albumin.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-30-81	Status: Ongoing

TITLE:

Renal Sequelae of Vasectomy

Start Date: 10 Apr 81		Est Comp Date: Apr 83
Principal Investigator Ian M. Thompson, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Urology		Associate Investigators: Mauro P. Gangai, M.D. C. Ritchie Spence, M.D., COL, MC
Key Words: Vasectomy Renal sequelae		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine, in a retrospective manner, if any changes in renal function occur after vasectomy.

Technical Approach: As per the requested change recently submitted, the protocol has been changed to incorporate 30 men who are randomly chosen from the Urology Clinic population who have undergone vasectomy in the past. These men will be compared to 30 randomly selected, age-matched controls for assessment of blood pressure and renal function (24 hour clearance of protein and creatinine).

Progress: As the first protocol's patient selection process was found to be unworkable, no patients have been studied.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-32-81	Status: Ongoing

TITLE:

The Role of Continuous Peritoneal Lavage in the Treatment of Severe Acute Pancreatitis

Start Date: 12 May 81		Est Comp Date: Jun 82
Principal Investigator Greg A. Bowman, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/General Surgery		Associate Investigators: James M. Kunkel, M.D., CPT, MC Michael J. Spebar, M.D., LTC, MC
Key Words: Pancreatitis Peritoneal lavage		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective; To determine the efficacy of continuous peritoneal lavage in decreasing the morbidity and mortality of severe acute pancreatitis.

Technical Approach: Patients diagnosed as having severe acute pancreatitis will be randomized into control and study groups. The control group will receive standard care for pancreatitis with surgical intervention when appropriate. The study group will undergo continuous peritoneal lavage with Inpersol for not less than 48 hours and not more than 5 days.

Progress: To date, no patients have been identified as having severe acute pancreatitis.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-40-81	Status: Ongoing

TITLE:

Anterior Vitrectomy for Aphakic Cystoid Macular Edema - Collaborative Study

Start Date: 15 Jun 81		Est Comp Date: Unknown
Principal Investigator Donald G. Griffith, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Ophthalmology		Associate Investigators:
Key Words: Vitrectomy Aphakic cystoid macular edema		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To learn what effect, if any, anterior vitrectomy has on persistent cystoid macular edema occurring after cataract extraction.

Technical Approach: patients with aphakic cystoid macular edema and evidence of vitreous abnormality will be randomly selected for vitrectomy or for nonsurgical management.

Progress: No patients have yet been enrolled in the study at BAMC.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-41-81	Status: Ongoing

TITLE:

Hearing Levels in Otherwise Healthy Children Who Were Exposed to Ultrasound While Fetuses

Start Date: 15 Jun 81		Est Comp Date: Mar 82
Principal Investigator Warner L. Bruner, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Otolaryngology		Associate Investigators: Joseph M. Brock, CPT, MSC Mark Russell, CPT, MSC
Key Words: Ultrasound		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To measuring hearing levels of otherwise healthy children who underwent diagnostic ultrasound in utero.

Technical Approach: Puretone audiometry through very high frequencies is performed on children exposed to diagnostic ultrasound in utero.

Progress: Difficulty in locating subjects who were exposed at BAMC have been encountered. Five or six ears tested so far have shown mild high frequency hearing loss as compared to established norms.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-57-81	Status: Ongoing

TITLE:

Cardiac Surgery Prospective Follow-up Project

Start Date: 20 Aug 81		Est Comp Date: Aug 84
Principal Investigator George F. Schuchmann, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Cardiothoracic		Associate Investigators: James B. Peake, M.D., LTC, MC
Key Words: Cardiac surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To follow-up patients who have had cardiac surgical procedures to assess: a. short-term outcome; b. long-term outcome; c. prognostic factors and relate above to work status and military service.

Technical Approach: Detailed preoperative, intraoperative, immediate post-operative and periodic long term data are being collected on every patient undergoing open heart surgery. This is being done in the form of question-naires with data processed via computer.

Progress: Our patient population and postoperative follow-up time thus far is insufficient to establish any trends. Tabulation of data has been delayed pending installation of data processing equipment and training personnel to operative the machine.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-60-81	Status: Ongoing

TITLE:

Post-Cholecystectomy Analgesia and Respiratory Function in Patients Treated with Epidurally Administered Morphine, Bupivicaine or Sterile Saline

Start Date: 1 Sep 81		Est Comp Date: Jan 82
Principal Investigator Chester E. Pruett, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Anesthesiology		Associate Investigators: Wallace H. Good, Jr., M.C., CPT, MC
Key Words: Epidrual morphine Analgesia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To document the postoperative respiratory function and analgesia obtained in patients undergoing right subcostal approach for cholecystectomy given epidurally applied morphine (the test drug) as compared to Bupivicaine (a previously reported modality) or sterile saline (a placebo control).

Technical Approach: Patients undergoing cholecystectomy will be randomly assigned to receive either epidural morphine, bupivicaine or sterile saline The anesthesia applied will be a single epidural injection of 10 ml of sterile test solution - either 5 mg preservative free morphine, 25 mg Bupivicaine, or sterile saline, followed by an inhalational -- relaxant (non-narcotic) oral endotracheal general anesthetic, an accepted balanced anesthestic for cholecystectomy. Postoperatively, the patients will be observed in the surgical recovery room for 24 hours post-injection, during which time the patient will be given all routine post-cholecystectomy medications and pain medication upon request. Patients will be encouraged to deep breathe, use the incentive spirometry and ambulate.

The data obtained will be evaluated as follows: Student t-test for duration of hospital stay, subtotal and total medication dosage, time to first ambulation and first meal, and spirogram analysis and non-parametric testing for pain report; chest x-ray; and surgical and nursing staff impression analysis.

Progress: This is a new study.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-40-80	Status: Ongoing

TITLE:

Evaluation of PO_2 Changes Associated with Intravenous Sedation for Outpatient Oral Surgery

Start Date: 1 Nov 80		Est Comp Date: 1 Jan 82
Principal Investigator Richard A. Kraut, D.D., LTC, DC		Facility Brooke Army Medical Center
Dept/Sec: Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: PO_2 changes Intravenous sedation Oral Surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the change from baseline PO_2 in patients undergoing outpatient oral surgery - (a) utilizing local anesthesia; (b) utilizing local anesthesia and intravenous Valium; and (c) utilizing local anesthesia and intravenous Valium and Sublimaze.

Technical Approach: Thirty patients will be selected for each of the three study groups. Patients will be selected from those patients who require removal of at least one maxillary and one mandibular impaced wisdom tooth. Patients will be assigned to study groups based on their request for sedation or local anesthesia. Patients requesting sedation will be alternately assigned to Group B and C.

The following monitors will be used on all patients included in this study:

1. ECG - a cardiac monitor utilizing a 2 channel oscilloscope with cardioverter/defibrillator connected in line.

2. A respiratory monitor with a digital rate display and a graphic display on the 2nd channel of the oscilloscope.

3. An automatic hands-off blood pressure monitor set for readings every 2 minutes.

4. A continuous cutaneous oxygen monitor.

Progress: 75% of data has been collected.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-62-81	Status: Ongoing

TITLE:

Effect of Supplemental Nasal Oxygen on the PO_2 of Patients Undergoing Outpatient Oral Surgery

Start Date: 23 Sep 81	Est Comp Date: Jan 82
Principal Investigator Richard A. Kraut, D.D., LTC, DC	Facility Brooke Army Medical Center
Dept/Sec: Department of Dentistry/Oral Surgery	Associate Investigators:
Key Words: Nasal oxygen PO_2	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the changes from baselin PO_2 in patients undergoing outpatient oral surgery with supplementsl nasal oxygen utilizing local anesthesia or local anesthesia plus intravenous Valium and Sublimaze.

Technical Approach: Twenty patients will be included in each of the study groups. Patients will be assigned to a study group based on their request for sedation or local anesthesia. The patients will be divided into four study groups. Group A will receive local anesthesia and supplemental oxygen via nasal prongs; B local anesthesia and supplement oxygen via a nasal mask; C intravenous sedation and supplement oxygen with nasal prongs; and D will receive intravenous sedation and supplemental nasal oxygen via a nasal mask. Heart rate, blood pressure and mean arterial blood pressure will be recorded every two minutes during the surgical procedure. A continuous graphic recording of the PO_2 will be generated via the transcutaneous oxygen monitor.

Progress: This is a new study.

Detail Summary Sheet

Date: 21 Oct 81	Proj No: C-63-81	Status: Ongoing

TITLE:

Evaluation of PO_2 Changes During Surgical Removal of Wisdom Teeth Utilizing General Anesthesia

Start Date: 23 Sep 81		Est Comp Date: Jan 82
Principal Investigator Richard A. Kraut, D.D., LTC, DC		Facility Brooke Army Medical Center
Dept/Sec: Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: PO_2 changes Wisdom teeth		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the changes in partial pressure of oxygen experienced by patients having wisdom teeth removed under general anesthesia.

Technical Approach: Twenty-five consecutive patients who request outpatient general anesthesia in association with the removal of their impacted wisdom teeth are to constitute the study group. The Roche Transcutaneous Oxygen Monitor to be utilized in this study will provide a written graphic record of the PO_2 of the patient. This is to serve as the data collection vehicle for collecint PO_2's in this study.

Progress: This is a new study.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: C-11-81	Status: Ongoing

TITLE:

Teaching the Language and Learning Disabled Soldier

Start Date: 4 Feb 81		Est Comp Date: Sep 82
Principal Investigator Judith Riggan, MAJ, AMSC		Facility Brooke Army Medical Center
Dept/Sec: Physical Medicine and Rehabilitation Service/Occupational Therapy		Associate Investigators:
Key Words: Learning Disabled Soldier		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine if Academy of Health Science students who are documented as "Language and Learning Disabled Adults" (LLD), can be helpped to succeed in their Advanced Individual Training program thus reducing attrition and/or failure rates at the Academy of Health Sciences.

Technical Approach: All soldiers beginning AIT in the 91E Dental Specialist Course are administered a questionnaire pertaining to past educational experiences during their initial orientation class. Those identified with potential learning disabilities are referred to Occupational Therapy, BAMC, for more definitive evaluation. Should the SM seem to be learing disabled, he/she is then given a battery of tests which evaluate sensory integrative dysfunction, performance/potential levels, and clinical observation of perceptual and psycholinguistic skills. Remediation in the Occupational Therapy Learning Abilities Clinic is then provided for these soldiers diagnosed as true Learning Disabled (LD).

Progress: Since initiation of this study, 56 soldiers have been individually screened by Occupational Therapy for possible learning disabilities. Fifteen of those revealed some academic weakness but could not be directly attributed to a learning disability, but rather limited learning potential and/or language barriers. Sixteen were evaluated and diagnosed as learning disabled. Eleven of those sixteen were formally treated in Occupational Therapy.

A "Past Education Questionnaire" has been developed as a screening tool and is used regularly during each 91E orientation class. A commercially available evaluation tool, which is statistically significant for documenting LD, has been purchased and is currently being implemented into the evaluation process.

C-11-81 (continued)

The course materials for the 91E Dental Specialist Course have been modified for the LD soldier who has difficulty reading: the technical manual is available on audio cassette; note taking has been significantly reduced; tests are given orally by the instructors or from audio cassette; visual aids (slides viewgraphs, etc.) have been reviewed and modified to reduce clutter, etc.

Inservice programs are being presented to the instructional staff of the Academy of Health Sciences pertaining to symptoms and treatment of the LD soldier. This inservice will become a routine presentation for all newly assigned AHS faculty during the Faculty Development Unit.

Further study is required, beyond the 91E course, to determine the number of LD soldiers who filter into the Academy of Health Sciences for Advanced Individual Training. These statistics are needed to help determine the need for an occupational therapist with SID/LD credentials on the Academy of Health Sciences TDA.

Detail Summary Sheet

Date: 6 Nov 81	Proj No:C-25-80	Status: Completed

TITLE:

Transcutaneous Electrical Nerve Stimulation to Control Postoperative Knee Pain.

Start Date: Jun 80	Est Comp Date:
Principal Investigator Stephen P. Shandera, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Sec: Physical Therapy	Associate Investigators:
Key Words: Transcutaneous Electrical Nerve Stimulation Postoperative Knee Pain	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate a treatment method, TENS, as a way to control post-operative knee pain.

Technical Approach: Eleven patients who had undergone reconstructive knee surgery were entered into the experimental group. These patients used TENS whenever needed for the first three days following surgery. Eight control patients did not use TENS. The amount of pain medicaiton used by the two groups was then compared.

Progress: All patients in the TNES group reported that the use of TENS helped control their pain. Although this group used less pain medication, the decrease was not significant. The results may have been affected by problems in experimental procedure and/or design.

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-30-80	Status: Completed

TITLE:

An Analysis of Factors Involved in Encouraging Research Among Physical Therapists

Start Date: Jun 80		Est Comp Date:
Principal Investigator Cary C. Bucko, 2LT AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators:
Key Words: Research Physical Therapists		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To provide a data-base for planning, administrative decision making, and/or policy formation.

Technical Approach: Questionnaires were sent to 500 randomly selected members of the American Physical Therapy Association active membership list of 1980. Various motivational factors were analyzed in this study to determine the reasons why physical therapists were not doing research.

Progress: The majority of respondents cited lack of time and lack of training in research methodology as their primary reasons for not conducting research. In addition, many therapists also indicated career advancement as a major motivating factor for doing research. Ideas and suggestions on how to rectify the situation were discussed.

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-43-81	Status: Completed

TITLE:

Measurable Support of Ankle Taping and Semi-rigid Support: A Comparative Study

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator Lauren Y. Hughes, 2LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators: Deborah M. Stetts, 2LT, AMSC
Key Words: Ankle taping Semi-rigid support		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To evaluate two methods of ankle support: a semi-rigid support system constructed of Surlyn^{R} and ankle taping.

To compare the effectiveness of these two methods in restricting successive active inversion.

Technical Approach: A comparison was made of the effectiveness of ankle taping utilizing the Gibney Basketweave and heel lock and a semi-rigid support constructed of Surlyn in restricting active inversion. Twenty-nine subjects had both methods applied concurrently such that one ankle was taped while the other was splinted. The first experimental group (14 subjects) was randomly selected to have the left nakle taped while the second experimental group (15 subjects) was randomly selected to have the left ankle splinted. Three measurements of maximum active inversion range of motion were taken on both ankles: (1) pre-support, (2) pre-exercise, and (3) post-exercise. The subject's active inversion range of motion was measured with the Leighton-Flexometer.

Progress: A comparison of measurements taken pre-exercise and post-exercise for both taping and splinting resulted in no significant difference in retention of support as measured in available degrees of active inversion range of motion. The findings of this study indicate that both methods of support are comparably effective in restricting inversion range of motion throughout a specific level and amount of exercise.

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-44-81	Status: Completed

TITLE:

Bilateral Comparison of Isokinetic Force Measurements of the Knee Extensors

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator Jill Bliss and Elise Dewit, 2LTs, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators:
Key Words: Knee extensors Isokinetic force		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine whether a significant difference exists between the torque generated by the knee extensors of the dominant and non-dominant lower members.

If such a difference exists, to observe whether is is accentuated or minimized at increasing limb velocities.

Technical Approach: Knee extension efforts were measured on the Cybex^{R} II Dynamometer at 30, 180, and 240^{o}/sec for 32 young adult subjects. At each of the three speeds, the highest peak torque was recorded for the left and right lower members.

Progress: Statistical application of a two-way analysis of variance with interaction showed no statistically significant difference in torque ($p < .01$) when comparing dominant versus non-dominant or left versus right lower members. In addition, the speed of limb movement did not have any effect upon the relationships studied.

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-45-81	Status: Completed

TITLE:

Factors Precipitating Hamstring Strains in Track Athletes.

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator William Bailey, 2LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators: William Bremiller, 2LT, AMSC
Key Words: Hamstring strains Track athletes		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To add to the existing knowledge of preventive sports medicine.

To assist supervisory personnel in planning training programs to avoid hamstring strains.

To predict the high risk individuals so that programs can be implemented to correct any deficiencies.

Technical Approach: A study of 95 high school track athletes was conducted to determine the most significant precipitators of hamstring injuries. The factors investigated included: bilateral hip joint flexibility, type of event, dominant leg, years of experience, age, sex, previous injury, and quadriceps:hamstring strength ratios as measured with a cable tensiometer.

Progress: Thirteen of the athletes sustained hamstring strains during the study. These 13 tended to be less flexible in the injured leg, were more experienced in track competition, and had a greater difference between quadriceps and hamstring strength in the injured leg. It was noted that 77% of all the injured athletes had sustained a previous injury to the injured leg. Certain events contributed to injury more than others, but age and sex showed no correlation to injury. Dominant leg correlated only in the hurdles.

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-46-81	Status: Completed

TITLE:

Relationship of Age, Sex, and Body Weight to Torque Production in Normal Dorsiflexion and Plantar Flexion

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator David A. Jerabek, 2LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators:
Key Words: Dorsiflexion Plantar flexaion		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To provide a data base for planning and setting goals for treatment and rehabilitation programs involving the dorsiflexors and plantar flexor musculature as well as the ankle itself for the dominant leg.

Technical Approach: This study was an attempt to define the normal limits of strength as related to age, sex, and body weight. Forty normal subjects, 20 male and 20 female, ages 23-60 were tested in plantar flexion and dorsiflexion on the Cybex Isokinetic Dynamometer (Cybex II^{R}).

Progress: Statistically significant correlations ($p < .05$) were found between age and torque, sex and torque, and age, sex and body weight and torque (torque in both dorsiflexion and plantar flexion). Regression equations, predicint 63% of the variation in dorsiflexion and 75% of the variation in plantar flexion were constructed.

Detail Summary Sheet

Date: 6 Nov 81 Proj No: C-47-81 Status: Completed

TITLE:

Treatment of Low Back Pain Using Acupressure Touch and Massage

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator Joseph J. Godges, 2LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators:
Key Words: Acupressure		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the efficacy of basic Tough for Health techniques as a way to control the symptoms of acute low back pain.

Technical Approach: Kinesiological muscle balancing techniques were applied to patients with acute or subacute low back pain to determine if these techniques offered immediate symptomatic relief. Pain level, spinal flexion, and abdominal strngth changes were measured in 13 patients who were treated with muscle balancing techniques taught in a basic Touch For Health coures, and in 13 patients who received a placebo treatment.

Progress: Touch For Health balancing significantly decreased pain, increased ability to perform a sit-up, and increased range of spinal flexion. Acupressure touch and massage techniques as taught in a basic Touch For Health class were effective in reducing the symptoms of acute low back pain.

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-48-81	Status: Completed

TITLE:

Analysis of Splinting as a Treatment for Carpal Tunnel Syndrome

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator William J. Tatu, 2LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators:
Key Words: Carpal tunnel syndrome		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To assess the results obtained by the Physical Medicine Service at BAMC in treating carpal tunnel syndrome with splinting.

Technical Appraoch: The records of twenty-five patients treated with resting hand splints for carpal tunnel syndrome were reviewed to assess the end result of treatment. Sixteen patients had bilateral involvement which brought the total to forty-one wrists. Distal sensory latencies, duration of symptoms and subjective complaints of the patients were extracted for statistical analysis.

Progress: Results indicated a statistically significant relationship between successful treatment and duration of symptoms ($p < .05$). Fourteen wrists failed to benefit from treatment, five of those patients underwent surgery. No correlation was found between initial severity of symptoms and successful treatment.

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-49-81	Status: Completed

TITLE:

Effect of Ice Facilitation on Grip Strength in Normals

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator Alfred B. Woodhead, 2LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators:
Key Words: Ice facilitation Grip strengths		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the effect of quick ice facilitation on the grip strength of normal individuals.

Technical Qpproach: Twenty-seven normal men and women were randomly assigned applications of quick or placebo ice to the flexor and extensor surfaces of their dominant arm. Grip strength was measured on a tensiometer at three points in the experiment. Grip strength was measured before application of ice or placebo, immediately after, and three minutes later. Six days after the first application, the subjects were tested again. Each person received the procedure with which they had not been tested.

Progress: An independent t-test revealed that the average difference between the mean grip strength immediately after quick ice facilitation, versus the mean grip strength after placebo icing, was not statistically significant ($t = \tau\ 55$, p = ns). Quick ice facilitation produced no significant change in grip strength of normal individuals, when applied simultaneously to the flexor and extensor surfaces of the forearm.

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-50-81	Status: Completed

TITLE:

Analysis of Methods of Measuring Pelvic Tilt

Start Date: 2 Jul 81		Est Comp Date:
Principal Investigator Matthew J. Taylor, 2LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators:
Key Words: Pelvic tilt Lumbar lordosis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate several clinical methods of measuring lumbar lordosis.

Technical Approach: There is no objective measure of lumbar lordosis practically available to the physical therapist. This study sought to statistically substantiate three suggested methods. The reliability of each method was determined in a pre-test, the least reliable being $\pm 1.85^{o}$ ($p < .05$). Thirty adults (18 men and 12 women), 23 to 79 years of age, were measured by each method and these measurements were then correlated with a radiographically obtained lumbosacral angle.

Progress: The three methods were mutually independent of the lumbosacral angle. These methods are reasonably reliable, but were not shown to be related to a clinically significant factor

Detail Summary Sheet

Date: 6 Nov 81	Proj No: C-55-81	Status: Completed

TITLE:

Electrical Skin Resistance Patterns as an Indicator of Postoperative Pain

Start Date: 18 Aug 81		Est Comp Date:
Principal Investigator Carol Echtenkamp, 2LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy Section		Associate Investigators: Sandra Webster, 2LT, AMSC
Key Words: Electrical skin resistance		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate electrical skin resistance patterns as an objective indicator of pain.

Technical Approach: Electrical skin resistance measurements were made on both knees of thirty normal and eight postsurgical, knee surgery patients.

Progress: The results show no statistically significant difference ($t = .6072$, p = ns) between the mean electrical skin resistance values for points on the right versus the left knees of the normal subjects. There was a statistically significant difference ($t = 2.4763$, $p < .05$) between the mean electrical skin resistance values for points on the involved versus the uninvolved knees of the postsurgical patients. This study indicates that the measurement of electrical skin resistance variations may represent an objective method for measuring pain.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: C-19-80	Status: Completed

TITLE:

Autotransfusion in Penetrating Trauma - The Feasibility of Processing Contaminated Blood.

Start Date: Apr 80		Est Comp Date:
Principal Investigator John D. Rumisek, M.D., CPT, MC		Facility Reynolds Army Hospital
Dept/Sec: Department of Surgery/General Surgery		Associate Investigators:
Key Words: Autotransfusion Penetrating trauma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To quantitate the capabilities and limits of the Haemonetics Cell SaverR blood processing system to remove bacterial contamination from blood for infusion.

To define the utility of the Haemonetics Cell Saver^{R} system for autotransfusion under conditions of severe penetrating trauma including battlefield injury for potential military utilization.

Technical Approach: The Haemonetics Cell Saver^{R} blood recovery system was employed to process a mixture made to simulate enteric contamination of intraperitoneal blood in severe penetrating abdominal trauma.

Progress: With the exception of terminal ileal or colonic spillage where bacterial counts can exceed 100 billion colonies per ml, intraperitoneal blood in penetrating abdominal trauma can be processed by the cell wash system for safe autotransfusion. Bacterial counts are less than 1000 colonies per ml to the level of the mid ileum and, along with bile, urine, fragments of bone and tissue, are effectively washed from the salvaged blood in logarithmic fashion. In these circumstances, use of autotransfusion of salvaged blood in penetrating trauma can be life saving, providing clean, fresh, and young autogenous red cells. However, until improvements in filtration and antibiotic augmentation can be demonstrated to eliminate the astronomical numbers of viable bacteria in even 0.1 ml of fresh stool, autotransfusion or processed fecal contaminated blood must be avoided, perhaps even in the most heroic of attempts.

APPENDIX A

SOUTHWEST ONCOLOGY GROUP

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7510	Status: Completed

TITLE:

Adjuvant Chemotherapy for Patients with Locally Advanced Adenocarcinoma of the Large Bowel.

Start Date: FY 76		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC
Key Words: Adjuvant chemotherapy		John D. Cowan, M.D., MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the effectiveness of the combination of MeCCNU + 5-FU as adjuvant chemotherapy.

To judge whether oral BCG adds to effectiveness.

Technical Approach: Patients with histologically proven Duke-C adenocarcinoma of the large bowel with no proven residua or metastatic disease and no prior chemotherapy or radiotherapy are eligible for entry into this protocol.

Treatment will conform with the schema outlined in the study protocol.

Progress: This study was recently closed. In two patients receiving chemotherapy plus BCG new primaries occurred at 26 months and 36 months. Total patient accrual was 620. Following the amendment to include a control arm, the recurrence rates were 36.5% (15/41) for the control arm, 30.5% (11/36) for chemotherapy and 31.2% (10/32) for chemotherapy and immunotherapy. Preamendment, the recurrence rate was 36.9% (52/141) for chemotherapy alone and 35.1% (42/134) for CT & IT.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7521	Status: Completed

TITLE:

Combination Chemotherapy with or without Immunotherapy in High Risk Melanoma Patients: An Adjuvant Study.

Start Date: FY 76		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Immunotherapy Melanoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy of BHD in preventing recurrence of disease and prolonging survival of patients who have received definitive surgical treatment for their primary lesions.

To determine the efficacy of BHD + BCG in preventing metastases and prolonging the disease-free interval.

To determine the immunocompetence of these patients.

Technical Approach: All patients with histologically confirmed diagnosis of malignant melanoma previously untreated with chemotherapy or radiotherapy, who are within four weeks of surgical excision of active disease, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Two hundred and forty-one patients were entered on the study. Patients receiving chemotherapy alone (BHD) have a longer disease free interval ($p = .09$) and survival ($p = .01$) than patients receiving chemotherapy (BHD) plus BCG. Age continues to be the most isgnificant prognostic factor, with patients less than 40 years of age and 60 years of age and older doing betterh with chemotherapy alone, as are patients with 2 or more extremity primaries and those with the greatest depth of invasion.

In conclusion, the BHD is superior to BHD + BCG.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7522	Status: Completed

TITLE:

Chemotherapy, Splenectomy with or without Immunotherapy in the Treatment of Chronic Myelogenous Leukemia

Start Date: FY 76	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chronic Myelogenous Leukemia Chmotherapy Splenectomy Immunotherapy	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To study the effects of chemotherapy, splenectomy and/or immunotherapy on leukemic cytogenetics, immune status, appearance of blastic transformation, and any influence in overall survival.

Technical Approach: All patients with confirmed diagnosis of benign phase CML not previously treated with any of the agents used in this study are eligible.

Treatment will conform with the schema outlined in the study protocol.

Progress: The study has been completed, and a manuscript is being prepared. However, final results of the study are not available for this report.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7524	Status: Completed

TITLE:
Chemotherapy in Stages III and IV Ovarian and Endometrial Cancer

Start Date: FY 76		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Ovarian cancer Endometrial Cancer Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To compare the effectiveness of chemotherapy alone vs chemo-immunotherapy for remission induction in Stages III and IV ovarian and endometrial carcinoma.

To test the effectiveness of chemotherapy plus immunotherapy vs chemotherapy in maintaining complete remissions.

To test effectiveness of continued chemotherapy plus immunotherapy vs chemotherapy in inducing complete remission or maintaining partial remissions in patients with occult disease at restaging or in patients achieving only partial remission during 12 month induction therapy.

Technical Approach: Patients with histologically confirmed ovarian carcinoma or endometrial carcinoma Stage III or IV with no prior chemotherapy or concurrent progestational agent therapy are eligible. Adenocarcinoma of cervix and germ cell of the ovary are eligible.

Therapy will be according to the schema outlined in the study protocol.

Progress: There has been statistical evidence that the ovarian cancer patients treated with AC + BCG had higher complete response-rates and longer median survival durations than those treated with AC alone.

For evaluation purposes, Stage III and Stage IV endometrial carcinoma patients were analyzed separately. Although the number of evaluable patients was small, no difference was seen between patients in CR or PR. Treatment was noted to be well tolerated and no difference was observed in the survival rates, response rates or response durations. It was concluded that BCG showed no evidence of adding any benefit when combined with Adriamycin and Cyclophosphamide.

SWOG 7524 (continued)

It was thought that the way each disease manifests itself could be a contributing factor as to why there was such a large difference in this regimen's effect on ovarian cancer (AC + BCG) as opposed to endometrial cancer.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7632	Status: Completed

TITLE:

Combined Modality for Recurrent Breast Cancer.

Start Date: FY 77		Est Comp Date:
Principal Investigator J. Dean McCracken, MD., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Breast cancer Hormonal therapy Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To establish the survival of breast cancer patients when treating the first recurrence with a coordinated hormonal-chemotherapeutic approach.

To determine the efficacy of a response to the antiestrogen Tamoxifen in predicing response to ablative surgery.

To correlate hormonal manipulations with estrogen and progesterone receptors where possible.

Technical Approach: Only patients who have been surgically and/or radiotherapeutically treated with the intent to cure their primary disease are eligible. In addition, patients with castration are eligible.

Progress: ER+ patients have an overall response rate of 50%. Postmenopausal patients have progressively longer durations of response the longer postmenopausal. It appears that response to tamoxifen may predicate response to oophorectomy, as 4/15 postmenopausal patients who achieved CR or PR on tamoxifen achieved CR or PR with oophorectomy; 5/22 premenopausal patients achieved CR or PR with oophorectomy after failing tamoxifen, but 0/10 patients with CR or PR on tamoxifen responded to oophorectomy. While none of 21 patients achieved CR or PR with oophorectomy after failing to respond to tamoxifen, approximately 50% of all patients had prior adjuvant chemotherapy.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7703	Status: Ongoing

TITLE:

Radiation Therapy in Combination with BCNU, DTIC or Procarbazine in Patients with Malignant Gliomas of the Brain

Start Date: FY 77		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Glioma Radiation therapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To compare the effectiveness of radiation therapy plus BCNU, radiation therapy plus DTIC, and radiation therapy plus Procarbazine for remission induction, duration of remission, and survival in patients with malignant gliomas of the brain.

Technical Approach: Patients with histologically confirmed primary central nervous tumors of the following histologic types are eligible: Astrocytoma, grades 3 and 4 (gliobastoma multiforme).

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 198 evaluable patients entered on this study. The CR + PR rates in the BCNU, Procarbazine and DTIC limbs are 37%, 17% and 40%, respectively. Patients 50 years or older have a lower CR rate (15%) than those patients under the age of 50 (27%). There are no statistically significant differences in duration of CR or CR + PR for the three treatment arms. The difference in response rates between BCNU and DTIC is nearly statistically significant ($p = .064$, uncorrected).

Detail Summary Sheet

Date: 22 Oct 81 Proj No: SWOG 7713/14 Status: Ongoing

TITLE:

Chemoimmunotherapy in non-Hodgkin's Lymphoma.

Start Date: FY 78	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemoimmunotherapy Non-Hodgkin's Lymphoma	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To compare the effectiveness, in terms of rate of response of two chemoimmunotherapy regimens (CHOP + Levamisole vs CHOP + Levamisole + BCG) against CHOP for remission induction in previously untreated patients with non-Hodgkin's lymphoma.

For patients proven to be in complete remission after induction, to compare the duration of documented complete response obtained by continued maintenance immunotherapy with Levamisole vs no maintenance therapy.

For patients with impaired cardiac function (not eligible for treatment with Adriamycin), with mycosis fungoides, or with only a partial response to 11 courses of treatment with CHOP-Levamisole + BCG, to estimate the complete response rate obtained by continued chemoimmunotherapy with COP + Levamisole.

To estimate the CNS relapse rate in patients with diffuse lymphomas when CNS prophylaxis with intrathecal cytosine arabinoside is used.

To continue to evaluate the impact of systemic restaging of patients judged to be in complete remission and the value of expert hematopathology review of diagnostic material from all cases.

To establish baseline and serial data on immunologic status in both chemoimmunotherapy groups.

Technical Approach: The patient must have the diagnosis of non-Hodgkin's lymphoma established by biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: There are currently 729 patients registered on the Induction Phase SWOG 7713. Of these patients 208 have had a second registration onto SWOG 7714. The study will continue to accrue new patients for approximately six more months.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7717	Status: Completed

TITLE:

Management of Patients with Metastatic Adenocarcinoma of Unknown Primary.

Start Date: FY 78		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Unknown Primary Metastatic Adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the yield of various diagnostic procedures in finding the site of tumor origin in patients who present with metastatic adenocarcinoma with no obvious primary source.

To compare the efficacy of combination chemotherapy using 5-FU, Adriamycin, and Cytoxan vs 5-FU alone in palliative management of patients with metastatic adenocarcinoma of unknown origin.

To assess the hematologic toxicity of the chemotherapy regimen on treated patients.

Technical Approach: Patients with metastatic adenocarcinoma with no obvious primary source are eligible for diagnostic evaluation. In addition they should meet the following criteria:

1. Should have histopathologic confirmation of their disease.

2. Patients must have measurable disease and an expected survival of six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: On the combination therapy arm there were 3/16 responders vs 0/19 on the single agent arm. Final evaluation of the data obtained from this study is not available.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7725	Status: Completed

TITLE: Continuous 5-Drug Induction with Intermittent CMPF vs CMPF + Levamisole for Maintenance in Patients with Estrogen Receptor Breast CAncer

Start Date: FY 78	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Estrogen receptor Breast cancer	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the respective effects of Levamisole on the duration of response and survival of patients with advanced breast cancer concurrently treated with maintenance chemotherapy after a successful remission induction trial of continuous Cooper regimen.

To accumulate data on immunologic variables under the conditions of chemotherapy alone and combined chemotherapy and immunotherapy with Levamisole of advanced breast cancer.

Technical Approach: Only patients prove to be ER negative are eligible. Patients with measurable lesions and no previous experience of chemotherapy other than adjuvant chemotherapy will be entered on the study.

Therapy will follow the schema outlined in the study protocol.

Progress: The median survival in this study was a little over one year. There seems to be no difference between the two arms in length of remission or survival. There appears to be no advantage to the addition of Levamisole.

Detail Summary Sheet

Date: 22 Oct 81		Proj No: SWOG 7727	Status: Ongoing

TITLE: Combination Chemoimmunotherapy Utilizing BCNU, Hydroxyurea and DTIC with Levamisole vs DTIC plus Actinomycin-D in the Treatment of Patients with Disseminated Malignant Melanoma.

Start Date: FY 78	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemoimmunotherapy Malignant melanoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine remission induction rates, remission duration, survival and toxicity in patients with disseminated malignant melanoma treated with BCNU, Hydroxyurea, and DTIC (BHD), BHD plus Levamisole, and intermittent single high dose DTIC plus Actinomycin-D in a prospective randomized clinical study.

Technical Approach: Patients with histologically proven disseminated malignant melanoma who have not been treated previously with any of the protocol agents shall be eligible. Patients must have measurable disease and estimated survival of at least two months.

Therapy will follow the schema outlined in the study protocol.

Progress: There continues to be no major difference in the three limbs of the study. Median survival for the DTIC + Actinomycin-D patients is 33 weeks; 27 weeks for BHD patients and 19 weeks for Levamisole patients. DTIC + Actinomycin-D appears to be most effective in poor risk patients. Immunotherapy has proved not to be of benefit in this study.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7765	Status: Ongoing

TITLE:

Adriamycin and Single Dose DTIC in Soft Tissue Sarcomas, Phase I/II.

Start Date: FY 79		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Soft tissue sarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the effectiveness and tolerance of Adriamycin and single dose DTIC in patients with metastatic sarcomas who have failed on higher priority treatment protocols.

Technical Approach: Eligible patients are those who have a biopsy-proven diagnosis of soft tissue or bony sarcoma with measurable metastases. Patients must have a life expectancy of at least six weeks. All patients must have some lesions which are measurable and can be followed for tumor responses.

Therapy will follow the schema outlined in the study protocol.

Progress: One hundred eight patients have been accrued so far with a broad distribution of malignancies, leiomyosarcoma being the most common. Six CR's and 10 PR's have been reported. Median survival is 30 weeks, females having a longer median survival than males.

This study remains open for bony sarcoma and mesothelioma patients only.

Detail Summary Sheet

Date: 22 Oct 81		Proj No: SWOG 7804	Status: Ongoing

TITLE: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.

Start Date: FY 78	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Gastric adenocarcinoma Chemotherapy Disease-free interval	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary.

Therapy will follow the schema outlined in the study protocol.

Progress: To date there are 57 patients registered. At present there are no differences between treatment arms.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7806	Status: Completed

TITLE:

Cis-Platinum in Refractory Epidermoid Carcinomas of the Esophagus.

Start Date: FY 78		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Refractory epidermoid carcinoma Cis-Platinum		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the response rate and survival, with some degree of precision, utilizing cis-diamminodichloroplatinum II (CACP) in the treatment of patients with squamous cell carcinoma of the esophagus which is growing despite more standard therapy.

Technical Approach: Patients must have a biopsy-confirmed diagnosis of epidermoid carcinoma of the esophagus in order to be eligible for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: The CR + PR response rate in fully + partially evaluable patients was 26%.

Detail Summary Sheet

Date: 22 OCT 81	Proj No: SWOG 7808	Status: Ongoing

TITLE:

Combination Modality Treatment for Stage III and IV Hodgkin's Disease MOPP 6.

Start Date: FY 79		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Hodgkin's disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a partial response at the end of six cycles of MOP-BAP.

To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when complete response has been induced with six cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligibile patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system.

Therapy will follow the schema outlined in the study protocol.

Progress: Currently, there are 112 eligible patients. Seventy-one patients are fully or partially evaluable, and of these 55 patients are fully evaluable. Seventy percent of the fully and partially evaluable patients are Stage IV. The arm that randomized patients with no prior radiotherapy who achieved CR to levamisole alone has been closed.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7811	Status: Ongoing

TITLE:

Brain Metastases Protocol.

Start Date: FY 79		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC
Key Words: Brain metastases		John D. Cowan, M.D., MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the effectiveness of combined radiation therapy and metronidazole (Flagyl) in the treatment of patients with brain metastases from primary malignancies outside the central nervous system, compared with radiation therapy alone, as determined by objective response (brain and/or CAT scan) and/or increase in functional neurologic level and duration of response.

To determine the toxicity of multiple dose administration of metronidazole and radiation therapy.

Technical Approach: To be eligible for this study, patients must have histologic proof of a primary malignancy. There must be clinical suspicion of brain metastases documented by isotope brain scan and/or CAT scan. Patients must either have measurable disease on brain/CAT scan and/or neurologic status level of 2-4. Patients must have an expected survival time of at least one month.

Therapy will follow the schema outlined int the study protocol.

Progress: One hundred fifty-two evaluable patients are needed on this study. There are 65 evaluable patients registered thus far. The overall response rates for treatment #1 (Decadron) and Treatment #2 (Decadron + Metronidazole) are 30% and 39%, respectively. Although accrual has been slow, the study remains open for new patient registration.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7813	Status: Ongoing

TITLE:

Ifosfamide in the Treatment of Resistant Disseminated Malignant Melanoma.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Disseminated malignant melanoma Ifosfamide		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and survival of Ifosfamide in patients with disseminated malignant melanoma who are either ineligible for higher priority studies or who have become resistant to standard therapy of a higher priority program.

To determine the qualitative and quantitative toxicity of Ifosfamide in patients with disseminated melanoma.

Technical Approach: All patients with histologically confirmed diagnosis of disseminated malignant melanoma who are not eligible for higher priority protocols or who have failed on standard regimens or higher priority programs are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-three patients have been entered on this study of which 22 are evaluable. All patients have been heavily pre-treated. One CR and four PR's have been reported.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7817	Status: Completed

TITLE:

Treatment of Advanced Germ Cell Neoplasms of the Testis.

Start Date: FY 79		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Germ cell neoplasm of testis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine in a randomized fashion the effectiveness of cis-diamminedichloroplatinum (DDP) given in the conventional low-dose schedule daily x 5 days versus high-dose intermittent treatment in remission induction of disseminated testicular cancer, when combined with vinblastine and bleomycin.

To determine the survival of patients who achieve a partial remission and are rendered disease-free by surgical removal of residual disease and maintained on the same chemotherapy as patients who achieved complete remission status on chemotherapy alone.

To determine the effectiveness of cyclophosphamide, actinomycin-D, adriamycin and vinblastine in the maintenance of remission status.

To document the nature and extent of the hemtologic and nonhematologic side effects of the various drug combinations.

Technical Approach: All patients with metastatic testicular cancer of germinal cell origin regardless of prior radiation therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One-hundred-six eligible patients were entered with 94 being evaluable. The complete remission rate for the high-dose cis-platinum was 61%, and 44% for the low-dose. Seventy-one percent of patients receiving high-dose cis-platinum had no evidence of disease after cytoreductive surgery compared to 53% for the low-dose patients. Also, 90% of the patients on the high-dose arm are disease-free at one year compared to 65% in the low-dose arm.

Detail Summary Sheet

Date: 22 Oct 81 Proj No: SWOG 7823/4/5/6 Status: Ongoing

TITLE:

ROAP-AdOAP in Acute Leukemia

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Immunotherapy Adult acute leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to AdOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival.

To determine the comparative toxicity of these regimens.

To determine whether late intensification therapy at 9 months after complete remission will improve long-term, disease-free survival.

To determine whether immunotherapy using levamisole for 6 months after 1 months of complete remission on chemotherapy improves disease-free survival.

To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia.

To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia.

To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 with a diagnosis of acute leukemia who have not received extensive therapy (defined as more than one course of any other chemotherapeutic agent or combination of agents) will be eligible for this study. The diagnosis of acute leukemia will be made on bone marrow smear, clot section and/or biopsy. An absolute infiltrate of 50% leukemic cells or greater is required.

Progress: At this time there appears to be no difference between rubidazone and adriamycin. In SWOG 7824, the number of patients is still too small to determine if CNS leukemia is being caused by multiple spinal taps. It is too early to draw any conclusions on either the SWOG 7825 or SWOG 7826 arms.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7827	Status: Ongoing

TITLE:
Combined Modality Therapy for Breast Carcinoma, Phase III

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Receptor positive (ER+) Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy.

To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone.

To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.

To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: To date there are 326 patients registered on the study, of which 185 are available for analysis. There have been 7 relapses, all in the ER- group, and 4 deaths, 3 of which occurred in the ER- group. It is too early to make any comparisons between treatment groups at this time.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: SWOG 7828	Status: Completed

TITLE:

Combined Modality Therapy for Extensive Small-Cell Carcinoma of the Lung.

Start Date: FY 79		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Small-cell carcinoma Toxicity		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To improve the complete response rate and long-term, disease-free survival of patients with extensive small-cell carcinoma of the lung.

To define, quantitate and quantify the toxicity of each regimen employed.

Technical Approach: There must be a diagnosis by the institutional pathologist of small-cell, undifferentiated carcinoma of the lung. Extensive small-cell carcinoma includes the following: 1) Any patient with evidence of metastatic spread beyond the hemithorax and supraclavicular nodes on either side; 2) Any patient with a cytology-positive pleural effusion; and 3) Any patient with prior radiation therapy to the primary tumor who presents with evidence of recurrent disease.

Patients meeting the above eligibility criteria will receive one of three treatment programs. Treatment program A consists of two standard drugs--Vincristine and Methotrexate. Treatment program B consists of Vincristine plus Adriamycin and Cyclophosphamide. Treatment program C consists of Vincristine, Adriamycin and Cytoxan plus VP-16. Therapy will follow the schema outlined in the study protocol.

Progress: The CR and PR response-rates among the three treatment arms were statistically identical; however, patients with a performance status of 0-1 had higher responses than those with a 2-4 performance status. A p value of .82 was observed in the survival rates of all treatment arms with a median survival of 30-31 weeks. Most importantly, reinduction patients had longer survival and longer time on study than maintenance patients.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7830 Status: Ongoing

TITLE: Carcinoembryonic Antigen as an Indicator for Second Look Surgery in Colorectal Cancer, a Randomized, Prospective Clinical Trial, Phase III.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Carcinoembryonic antigen Duke's B and C colorectal cancer	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine whether serial carcinoembryonic antigen (CEA) assays, following curative surgery, for Duke's B and C colorectal cancer leads to earlier detection of recurrence than standard follow-up procedures.

To determine whether recurrence detected through elevated CEA values, plus "standard clinical follow-up", leads to an improvement in the percentage of patients converted to no evidence of disease status following a second look surgery as opposed to recurrence detected by "standard" clinical means alone.

To determine whether there is a difference in crude survival between the CEA follow-up group and the standard follow-up group.

Technical Approach: To be eligible, the patient must have a completely resected Duke's B or C adenocarcinoma of the colon or rectum. Careful attention should be given to the examination of the liver. Suspicious areas should be biopsied to rule out metastatic disease. CEA values at 30 days post-initial resection myst be normal, i.e., nonsmokers < 2.5 ng/ml, smokers < 5.0 ng/ml. Patients may be entered on the basis of institutional CEAs done 4-6 weeks post-op with normal defined above.

Eligible patients will be placed in one of two follow-up plans. Plan A - Patients placed on this regimen will be closely monitored for the development of recurrent disease by means other than CEA with physical examinations, blood chemistry tests, nuclear medicine scans and x-rays at intervals from every two months to one year. Plan B is the same as Plan A with the exception that a CEA blood test will be done every two months for two years.

Progress: The surgical protocol for CEA as an indicator for second-look surgery was closed because of inadequate patient registration. It appeared biased, as the value of CEA is already too well established to perform such a study.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7832	Status: Completed

TITLE:

Evaluation of Chlorozotocin in Lung Cancer.

Start Date: FY 79		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chlorozotocin Lung cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results·

Objectives: To determine whether chlorozotocin has significant activity as determined by response rate and median duration of response, against small cell, large cell, adenocarcinoma or squamous carcinoma of the lung.

To observe for toxicities of chlorozotocin not yet described and better define the known toxicities.

To determine factors predisposing to excessive toxicity to this agent.

Technical Approach: To be eligible, the patient must have histologically proven lung cancer and must have measurable lesions. Patient must be off all prior anticancer treatment for at least three weeks and recovered from all acute toxicities of prior treatment.

The anticipated accrual rate to this study is 8-10 eligible patients/month. At this rate it would be feasible to accrue the necessary 120 response-evaluable patients allowing for an overall inevaluability rate of 20-25%.

Therapy will follow the shcema outlined in the study protocol.

Progress: This study has been completed. A manuscript has been prepared and will be submitted to Cancer Treatment Reports for publication.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7841	Status: Ongoing

TITLE:

Phase II-III Comparison of FAM vs FAM + Vincristine vs Chlorozotocin in the Treatment of Advanced Gastric Adenocarcinoma.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Gastric adenocarcinoma Chlorozotocin	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine whether or not vincristine increases the effectiveness (as determined by response rate and survival) of 5-FU plus mitomycin-C plus Adriamycin (FAM) in the treatment of advanced, previously untreated gastric adenocarcinoma.

To determine the efficacy, as determined by response rate and survival of chlorozotocin in the treatment of previously untreated gastric adenocarcinoma.

To determine by crossover, after relapse or failure on FAM, V-FAM or chlorozotocin, the effectiveness as determined by response rate and survival, of the alternate treatment in advanced gastric adenocarcinoma with prior therapy.

To determine the toxicities of such treatments.

Technical Approach: Patients must have histologically proven adenocarinoma, Stage IV in extent, to be eligible for this study. They must not have received prior chemotherapy nor should they have received radiotherapy within four weeks of entry. Patients must have a minimum life expectancy of 6 weeks and a performance status of 0-3 in order to be eligible.

The protocol has been amended and the current title and arms being used are V-FAM versus m-AMSA.

Progress: The study has shown that V-FAM offers no advantage over FAM, and only adds vincristine's toxicity. The protocol will be amended replacing m-AMSA with DHAD.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: SWOG 7860	Status: Ongoing

TITLE:

Evaluation of MGBG in Solid Tumors and Refractory Hematologic Malignancies

Start Date: 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Solid tumor MGBG Hematologic malignancy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine response rate and remission duration with primary weekly intravenous therapy using MBGB in patients with advanced esophageal, breast, pancreatic, colorectal, and head and neck carcinomas and lymphoma.

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: Patients must have pathologically verified histologic diagnosis of cancer. MBGB is intended as initial chemotherapy for patients with inoperable or disseminated renal, esophageal, and pancreatic carcinoma. It is intended for use in patients with other forms of advanced malignancy (breast, head and neck, colorectal, lymphoma and multiple myeloma) if their disease has become progressive after initial chemotherapy and who are not candidates for SWOG studies of higher priority.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was only recently opened to groupwide participation. No data are available at this time.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7863	Status: Completed

TITLE:

Concurrent Chemotherapy-Radiation Therapy of Selected Head and Neck Cancer.

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Head and neck cancer Radiation therapy Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To assess the local and systemic toxicity of the concurrent administration of the chemotherapeutic agents, bleomycin and hydroxyures with super voltage radiotherapy in the treatment of locally advanced squamous cancer of the head and neck.

To determine the maximum tolerated dose of both chemo- and radiotherapy when given according to the proposed regimen.

Technical Approach: Patients with locally advanced squamous cell carcinoma of the head and neck who are candidates for definitive or palliative radiotherapy are eligible. Patients must have histologic confirmation of their disease and must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: The complete remission response rates vary with dose levels #1 (38%) and #4 (36%) having lower response rates than dose levels #2 (56%) and #3 (55%). The median response duration has been 29 weeks for all patients. The CR + PR rate was 83%.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7902	Status: Ongoing

TITLE:

Combined Modality Therapy for Head and Neck Cancer.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Head and neck cancer Chemotherapy Radiation therapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the survival of Stage III and IV squamous cell carcinoma of the tongue, oral cavity, tonsil, oropharynx, hypopharynx and larynx subjected to radiation therapy followed by surgical excision, if possible, vs survival of patients subjected to chemotherapy with Cis-platinum, Oncovin and Bleomycin (COB), followed by radiation therapy and surgical excision if possible.

To determine the incidence and extent of complications arising from chemotherapy and radiotherapy followed by head and neck surgery vs radiotherapy and head and neck surgery.

Technical Approach: Previously untreated patients with a histologically confirmed diagnosis of advanced inoperable squamous cell carcinoma of the head and neck, Stages III and IV, of the oral cavity, tongue, tonsil, oropharynx, hypopharynx and larynx are eligible. There must be an evaluable lesion(s). Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 34 patients registered thus far. Of the 23 eligible patients there are 7 FE+PE patients on both treatment arms. On treatment arm #2 there have been 3 remissions with one patient relapsing 8 weeks after response.

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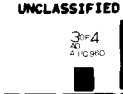

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7904	Status: Ongoing

TITLE: Hexamethylmelamine vs FAC in Advanced Transitional Cell Bladder Carcinoma in Patients with Impaired Renal Function, Phase II-III

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Transitional cell bladder carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To compare the efficacy (response rate) of hexamethylmelamine vs FAC (5-Fluorouracil, Adriamycin and Cyclophosphamide) in locally recurrent or disseminated transitional cell bladder carcinoma, in patients with impaired renal function, with crossover upon treatment failure.

Technical Approach: Patients with histologically proven T_4 transitional cell bladder carcinoma, if there is a contraindication to radical surgery or radiotherapy, and recurrent or residual cases after surgery, radiotherapy or both; and M_1 cases with liver, osseous, pulmonary or other metastases are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-two patients have been entered on this study to date, and the accrual rate is improving.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7906	Status: Ongoing

TITLE:

Multidrug Adjuvant Chemotherapy in Non-Metastatic Osteosarcoma - Comparison of Conpadri I with Compadri V, Phase III.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Osteosarcoma, nonmetastatic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare disease-free survival in patients with nonmetastatic osteosarcoma treated with (a) Conpadri-I using cyclophosphamide, vincristine, phenylanine mustard, and Adriamycin with (b) those treated by Compadri-V using high-dose methotrexate with citrovorum factor in addition to those drugs mentioned above.

To determine prognostic differences in the subtypes of osteogenic sarcoma.

For patients undergoing treatment on the Compadri-V arm, to evaluate the effect of preoperative high-dose methotrexate on the amputation specimen.

Technical Approach: All patients with histologically established diagnosis of osteosarcoma without metastases may be registered for the study. Patients must be registered before amputation.

Therapy will follow the schema outlinedin the study protocol.

Progress: This study is ongoing as a Pediatric Oncology Group protocol.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7910	Status: Completed

TITLE:

Evaluation of Estrogen-Antagonist in the Management of Refractory Large Bowel Tumors, Phase II.

Start Date: FY 79		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Estrogen receptors Colorectal tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To help judge whether there is any therapeutic significance in humans to the laboratory observation that some colorectal tumors, in men and women, have estrogen receptors as determined by response rate to tamoxifen.

Technical Approach: Patients with biopsy confirmed diagnosis of adenocarcinoma of the large bowel are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Tamoxifen's toxicity is virtually nonexistent. Median survival for these patients is 27 weeks. Survival curves for patients who have received prior chemotherapy versus those who have not, show an advantage for previously untreated patients (20 weeks versus 25 weeks). Patients entering the study with a performance status 0-1 showed a survival advantage over those entering with a performance status of 2 (34 weeks versus 13 weeks, respectively). Patients who underwent biopsy for ER determination had a considerably shorter survival time than those who did not (8 weeks versus 31 weeks, respectively).

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7912	Status: Completed

TITLE:

Gallium Nitrate in Patients with Malignant Lymphoma - Hodgkin's and Non-Hodgkin's, Phase II.

Start Date: FY 79		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Hodking's lymphoma Non-Hodgkin's lymphoma Gallium nitrate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy, as measured by response rate, of gallium nitrate in patients with malignant lymphoma, both Hodgkin's and non-Hodgkin's types, in patients who have received prior therapy and are not eligible for higher priority studies.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients with malignant lymphoma who are not eligible for higher priority protocols are eligible. Patients must have a life expectancy of at least 6 weeks and clearly measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Of the 31 patients registered on this study, three patients have had partial remissions for 4, 5 and 13 months. Of the 31 patients registered, 5 patients were Hodgkin's, 20 patients non-Hodgkin's and 6 patients of unknown histology. Gallium Nitrate appears to have some anti-tumor activity in non-Hodgkin's patients. However, there were not enough Hodgkin's disease patients to evaluate the study's objectives for this group.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7915	Status: Completed

TITLE:

Combination Chemotherapy in the Therapy of Advanced Carcinomas of the Salivary Glands.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Salivary gland carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine, and to document, the efficacy, as determined by the response rate, of a combination of Adriamycin, Cytoxan, and 5-Fluorouracil in the chemotherapeutic management of advanced, rapidly growing, epithelial tumors of the salivary glands not amenable to surgery or radiotherapy.

Technical Approach: Patients with biopsy-confirmed diagnosis of carcinoma arising in one of the major or minor salivary glands are eligible. The tumor must be aggressively and actively growing and all rational surgical and radiotherapy alternatives must have been exhausted.

Therapy will follow the schema outlinedin the study protocol.

Progress: Results were encouraging in the three patients treated. It is hoped that the study will be reopened at a later date.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7916	Status: Ongoing

TITLE:

Phase II Evaluation of Gallium Nitrate in Metastatic Urological Malignancies: Testicular, Bladder, Prostate and Kidney

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Metastatic urological malignancies Gallium nitrate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of Gallium Nitrate, as determined by response rate, duration of response and survival, in patients with metastatic urological malignancies which include: testicular, bladder, prostate and kidney; who have failed on higher priority treatment protocols.

Technical Approach: All patients no eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic urological malignancies are eligible. Patients should not have had more than two previous types of combination or single agent chemotherapy trials. Patients must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-seven patients have been entered: 17 renal cell, 16 prostatic, and 4 bladder carcinomas. There have been no responses in either the kidney or prostate categories. It was recommended that this study be closed to testicular, prostate and kidney patients. There has been one complete response in 4 patients treated for bladder cancer. The study will remain open for bladder patients only.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7917	Status: Completed

TITLE:

Gallium Nitrate in Previously Treated Patients with Metastatic Breast Cancer, Phase II.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Metastatic breast cancer Gallium nitrate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy (as determined by response rate and median duration of response) of Gallium Nitrate in metastatic carcinoma of the breast who have failed standard therapy.

To determine if an initially positive Gallium scan predicts response.

Technical Approach: To be eligible, patients must have histologic proof of breast cancer currently stage IV in extent. There must be measurable disease. Patients must not be eligible for higher priority protocols and should have had a previous trial with appropriate standard therapies (Cooper's regimen and/or hormonal manipulation).

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-six patients have been entered on the study, and twenty-two are fully or partially evaluable. There were no responses or improvements in the 22 patients. The median number of doses of gallium nitrate was 3. Median performance status was 1.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7918	Status: Completed

TITLE:
Evaluation of m-AMSA in Lymphoma - Hodgkin's and Non-Hodgkin's.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Hodgkin's lymphoma Non-Hodgkin's lymphoma m-AMSA		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the antitumor activity as determined by response rate and duration of response of m-AMSA used in a single dose schedule in patients with Hodgkin's and non-Hodgkin's lymphoma, who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, advanced Hodgkin's or non-Hodgkin's lymphoma are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The study confirms that m-AMSA is an active agent with remission seen in 7 of the 38 evaluable cases. The duration of the CR's is 9 months and 12+ months. The partial remissions are less impressive at 1, 2, 3 and 4 months.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7920	Status: Ongoing

TITLE:

m-AMSA in Hepatocellular Carcinoma, Gallbladder Carcinoma and Bile Duct Carcinomas, Phase II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Hepatocellular carcinoma Gallbladder carcinoma Bile duct carcinoma m-AMSA		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of m-AMSA at a dose of 120 mg/M2 IV every three weeks in producing regressions or remissions in patients with hepatocellular, bile duct, and gallbladder carcinoma.

Technical Approach: All patients who have histologically confirmed hepatocellular carcinoma, gallbladder carcinoma or bile duct carcinoma beyond hope of surgical cure are eligible. There must be histologic proof of residual, recurrent or metastatic carcinoma. Patients must have measurable disease and a life expectancy of at least 4 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: To date there are 23 hepatoma, 10 gallbladder and 8 bile duct patients entered on study. This study remains open for gallbladder and bile duct only. Responses to date: hepatoma 2 PR' and 2 improvements; gallbladder - 1 PR and 1 improvement; and bile duct - 1 PR.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7921	Status: Completed

TITLE:

Methyl-Gloxyl BIS-Guanylhydrazone (MGBG) in Metastatic Carcinoma of the Breast.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Breast carcinoma Methyl-Gloxyl BIS-Guanylhydrazone		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine response rate and remission duration with weekly intravenous therapy using MGBG in patients with carcinoma of the breast who have failed on higher priority treatment protocols.

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic carcinoma of the breast are eligible. Patients must have clearly measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There were 54 patients evaluable for response, all had received prior extensive chemo- or hormonal therapy. There was 1 CR documented at autopsy; 1 improvement and 10 patients with stable disease lasting a median of 6 weeks.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7922	Status: Ongoing

TITLE: Combination of CTX, Adria and Cis-Platinum vs m-AMSA in Patients with Advanced Transitional Cell Cancer of the Urinary Bladder with Good Renal Function, Phase II-III.

Start Date: FY 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Transitional cell bladder cancer	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate to the combination chemotherapy of CAP vs m-AMSA in patients with advanced transitional cell carcinoma of the urinary bladder not amenable by surgical resection and/or radiotherapy, who have good renal function.

To determine the response rate to CAP vs m-AMSA after failure or progression on either arm upon crossover to the alternate treatment arm.

Technical Approach: Patients with histologic diagnosis of transitional cell carcinoma of the urinary bladder, Stage IV, or patients who have failed on previous surgery and/or radiotherapy are eligible. Patients must have measurable disease and a life expectancy of at least 8 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 21 patients entered. The majority are too early to evaluate. Of the 9 evaluable patients, there have been 2/4 responses to m-AMSA and 3/5 to the combination treatment.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7923	Status: Completed

TITLE:

Gallium Nitrate in Metastatic Squamous Cell Carcinoma and/or Local Recurrent Squamous Cell Carcinoma of the Head and Neck.

Start Date: FY 80	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Gallium nitrate Squamous cell carcinoma of head and neck	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy as determined by response rate of Gallium Nitrate in patients with metastatic squamous cell carcinoma and/or local recurrent squamous cell carcinoma of the head and neck who have failed on higher priority treatment protocols.

To determine if Gallium scan results may be predictive of anti-tumor effect.

Technical Approach: All patients not eligible for higher priority SWOG protocols with histologically proven, incurable, advanced, metastatic squamous cell carcinoma or local recurrent squamous cell carcinoma of the head and neck are eligible. Patients must have clearly observable and/or measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Eighteen patients have been registered thus far, with 9 fully or partially evaluable patients, 7 too early to evaluate and 1 patient not evaluable. Thus far there have been no responses seen.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7924	Status: Ongoing

TITLE:

Multimodal Therapy for Limited Small Cell Carcinoma of the Lung, Phase III.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Small cell carcinoma of lung		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy of sequentially alternating mutally noncross-resistant, multidrug regimens in remission induction and intensification therapy in patients with limited small cell lung cancer.

To determine the value of chest radiotherapy added to intensive systemic chemotherapy in reducing chest recurrences and in improvement of survival.

To determine the relative efficacy and toxicity of low-dose, extensive chest radiation when used in close chronologic sequence with systemic multiagent chemotherapeutic regimens.

To determine whether radiotherapy ports should be set according to tumor size prior to or after induction chemotherapy.

To determine the value of combined systemic chemotherapy and radiotherapy in the control of bulky chest disease.

Technical Approach: Patients with histologically or cytologically proven small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease".

Therapy will follow the schema outlined in the study protocol.

Progress: In 94 evaluable patients treated with chemotherapy alone, 35% have achieved CR, 47% PR, with an overall response rate of 82%. Sex, performance status and tumor size seem to have no effect on remission durations. At this time the median survival is 53 weeks; however, it is still early.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7925	Status: Ongoing

TITLE:

Chemoimmunotherapy in Stages III and IV Ovarian Carcinoma: A-C plus BCG, vs A-C plus Cis-Platinum, vs A-C plus Cis-Platinum plus BCG, Phase III.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Ovarian carcinoma Chemoimmunotherapy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum for remission and induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the effectiveness of A-C + Cis-Platinum vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival in patients with Stage III and IV ovarian carcinoma.

To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the toxicities of the A-C + BCG, A-C + Cis-Platinum and A-C + Cis-Platinum + BCG regimens.

Technical Approach: Only patients with epithelial type neoplasms will be eligible for this study. The patient must have histologically confirmed diagnosis of ovarian carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: It has been noted that patients who receive cis-platinum enter remission earlier than those who do not. The previous amendment utilizing intravenous Cytoxan instead of the oral form is proving successful.

Detail Summary Sheet

Date: 23 Oct 81 Proj No: SWOG 7927/8 Status: Ongoing

TITLE:

Chemotherapy for Multiple Myeloma, Phase III.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Multiple myeloma Chemotherapy	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the effectiveness of four different drug combinations for remission induction in previously untreated patients with multiple myeloma.

For patients with a 75% tumor reduction, to evaluate the role of 12 months of chemotherapy maintenance with VCP or VCP plus levamisole, when compared with previous experiences.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma will be eligible for this study. Patients should jave objective evidence of and be symptomatic from complications due to myeloma.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been good. As yet, no analysis has been prepared.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7934	Status: Completed

TITLE:

Evaluation of Acridinylamino-Methansesulfon-M-Anisidide (AMSA) in Metastatic Squamous Carcinoma of the Head and Neck, Phase II.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Adridinylamino-Methansesulfon-M-Anisidide Head and neck, metastatic squamous carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the antitumor activity, response rate and duration of response in patients with metastatic squamous cell carcinoma of the head and neck who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies, with histologically proven, incurable, advanced squamous cell carcinoma of the head and neck are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-nine patients have been entered on the stucy, and sixteen have been evaluated for response. Of the 7 patients evaluated for response in the good-risk treatment arm, 1 patient had stable disease with 6 patients having increasing disease. In the poor-risk group, one patient showed a partial response, with 8 patients having increasing disease. Too many patients had received prior chemotherapy making them poor-risk and ineligible for the higher dose of m-AMSA.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7935	Status: Completed

TITLE:

Chemotherapy of Functioning and Nonfunctioning Islet Cell Carcinoma with Chlorozotocin.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Islet cell carcinoma Chlorozotocin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To study the response of functioning and non-functioning islet cell carcinomas to chlorozotocin.

To obtain pathology materials for review on all patients entered into this study.

Technical Approach: Eligible patients must have biopsy-proven islet cell carcinoma not amenable to further surgical therapy, and a minimum life expectancy greater than 6 weeks. All patients must have objectively measurable disease or a significant biochemical abnormality specific for their islet clel tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have shown improvement, and there have been no other responses.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7936	Status: Ongoing

TITLE: Evaluation of Mitomycin-C + Vincristine + Bleomycin + Cis-Platinum vs Mitomycin-C + Cis-Platinum vs Cis-Platinum in the Treatment of Disseminated Carcinoma of the Uterine Cervix, Phase II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Uterine cervix carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate, duration of responses, and survival of (1) cis-platinum alone, (2) cis-platinum combined with mitomycin-C, and (3) cis-platinum with mitomycin-C, vincristine, and bleomycin, in patients with advanced squamous cell carcinoma of the cervix no longer amenable to surgery or radiation therapy.

To document the nature and extent of the hematologic and non-hematologic side effects of the above three drug regimens.

Technical Approach: All patients with incurable squamous cell carcinoma of the uterine cervix who are not candidates for surgery or radiotherapy and are not eligible for higher priority SWOG studies are eligible. Patients must have no uncontrolled active or potentially active site of infection, must have at least one measurable lesion and must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There is a significant problem with patient accrual with only 21 patients registered thus far. Because there is already considerable Phase II data on cis-platinum in cervical cancer, it was decided that the cis-platinum alone arm could be dropped to aid in the study's progress.

Detail Summary Sheet

Date: 23 Oct 81	Proj No: SWOG 7937	Status: Ongoing

TITLE:

Evaluation of m-AMSA in Metastatic Carcinoma of the Genitourinary Tract Except Renal Carcinoma, Phase II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Metastatic genitourinary tract carcinoma m-AMSA		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity of AMSA, as determined by response rate, duration of response, and survival, in patients with metastatic carcinoma of the genitourinary tract who have failed on higher priority treatment prtocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic carcinoma will be eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol

Progress: Only five patients have been entered; all are too early to evaluate.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7940/1/3	Status: Ongoing	

TITLE:

Evaluation of 5-FU vs a Phase II Drug in Metastatic Adenocarcinoma of the Large Bowel, Phase II-III.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Metastatic adenocarcinoma of large bowel MGBG Gallium Nitrate DHAD	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the relative activity of a phase II drug (MGBG SWOG 7941, Gallium Nitrate SWOG 7943, DHAD SWOG 7944) in previously untreated patients with disseminated colon and rectal cancer.

To compare the survival of patients with disseminated colon cancer receiving a Phase II agent (MGBG/Gallium Nitrate/DHAD) as first therapy to the survival of patients receiving fluorinated pyrimidine 5-Fluorouracil (5-FU) therapy first.

To determine the effect of a previously administered Phase II drug on the response rate seen with 5-FU in patients with disseminated colon and rectal cancer.

Technical Approach: Eligible patients must have biopsy proven adenocarcinoma arising from the colon or rectum. Patients must have clinically measurable recurrent or disseminated disease to qualify for the study. Obstructive lesions in the colon and rectum must have been bypassed or adequately maintained by decompression measures. Patients must have a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been no responses to date on the 5-FU arm. There is no significant difference between 5-FU and MGBG between good and poor risk, male and female. In both arms there was a significant difference between performance status groups 0-1 versus 2, with a median survival of 25 versus 18 weeks respectively. Twenty-five patients have been placed on the DHAD arm, 4 have crossed-over to 5-FU; toxicity has been minimal.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: SWOG 7942	Status: Ongoing

TITLE:

Appendix VI SWOG 7940, Evaluation of Indicine-N-Oxide in Metastatic Adenocarcinoma of the Large Bowel, Phase II

Start Date: 11 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Indicine-N-Oxide Metastatic adenocarcinoma Large bowel	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Periodic Review Results: Continue	

Objectives: To determine the efficacy of indicine-N-oxide administered in a single dose schedule in patients with advanced adenocarcinoma of the colon and rectum by evaluation of response rates.

To determine more completely the nature and degree of toxicities of indicine-N-oxide in an expanded Phase II study.

Technical Approach: Eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: SWOG 7944	Status: Ongoing

TITLE:

Appendix VI SWOG 7940, Evaluation of DHAD in Metastatic Adenocarcinoma of the Large Bowel, Phase II

Start Date: 11 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: DHAD Metastatic adenocarcinoma Large bowel	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and remission duration in patients with colorectal carcinoma treated with dihydroxyanthracenedione in a single-dose, every 3-week schedule.

To define the qualitative and quantitative toxicities of dihydroxyanthracenedione.

Technical Approach: Patient eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-five patients have been placed on the DHAD arm, 4 have crossed-over to 5-FU; toxicity has been minimal.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 7945	Status: Ongoing

TITLE:

Appendix VI SWOG 7940, Evaluation of AZQ in Metastatic Adenocarcinoma of the Large Bowel, Phase II Portion

Start Date: 25 Sep 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Adenocarcinoma large bowel	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity of AZQ in colorectal carcinoma by determination of response-rate and remission duration.

To further determine the nature and extent of AZQ toxicity in a Phase II study.

Technical Approach: Patient eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlinedin the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7956	Status: Ongoing

TITLE:

Study of Postinfarction Nephrectomy and Medroxyprogesterone Acetate (Depo-Provera) in Metastatic Renal Cell Carcinoma.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Metastatic renal cell carcinoma Postinfarction nephrectomy Depo-Provera		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate and survival patterns in patients with disseminated renal cell carcinoma treated with postinfarction nephrectomy.

To determine the response rate and survival patterns of patients with disseminated renal cell carcinoma who relapse or do not respond to post-infarction nephrectomy when treated with Depo-Provera.

Technical Approach: Patients with measurable disseminated renal cell carcinoma who have not had removal of the primary cancer and in whom the metastatic disease is not resectable at the time of nephrectomy are eligible. Patients must have an expected survival of at least 3 months.

Therapy will follow the schema outlined in the study protocol.

Progress: More than 20 patients have been entered on study with 14 being evaluable. The 14 evaluable patients are categorized as follows: 1 PR, 4 stable disease, 8 no response, and 1 postoperative mortality. Nine patients received Depo-Provera resulting in 1 PR, 1 stable disease, and 7 no responses.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7958	Status: Ongoing

TITLE:

Evaluation of m-AMSA in Metastatic or Recurrent Epithelial Carcinomas of the Female Genital Tract.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncoloty	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Epithelial carcinoma of female genital tract m-AMSA	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity of AMSA in patients with metastatic or recurrent epithelial carcinomas of the ovary, endometrium, cervix, vagina or vulva who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of AMSA in patients treated by the split-course three-day schedule.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven incurable, advanced, metastatic or recurrent epithelial carcinoma of the ovary, endometrium, cervix. vagina or vulva are eligible. Patients must have clearly measurable disease and a life expectancy of 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: As a whole, AMSA does not seem to be effective in epithelial Gyn carcihomas. However, the agent did seem to be well tolerated on the daily x 3 schedule. Of the 15 patients who were evaluated, no complete or partial responses occurred. The study was closed to ovarian patients.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7959	Status: Completed

TITLE:

Evaluation of Methyl-Gloxyl Bis-Guanylhydrazone (MGBG) in Metastatic Renal Carcinoma.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Metastatic renal carcinoma Methyl-Gloxyl Bis-Guanylhydrazone (MGBG)		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and remission duration with weekly intravenous therapy using MGBG in patients with metastatic renal carcinoma.

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: Eligible patients are those with a histologically proven diagnosis of incurable, advanced, metastatic renal cell carcinoma. All patients must have measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Of the 58 evaluable patients, 3 showed a partial response (5% response rate). This Phase II study does not confirm the earlier, more encouraging Phase I trial results.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7960	Status: Completed

TITLE:

Colchicine in Refractory Hodgkin's Disease, CLL, Lung and Breast Cancer.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Refractory Hodgkin's, CLL, Lung and Breast Cancer Cochicine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the maximum dose of colchicine which may be safely administered on a once weekly basis.

To determine the response rate (standard error ± 10%) to weekly, intravenous cholchicine in each of the tumor types tested.

To determine quantitative and qualitative toxicity of the drug on this schedule.

Technical Approach: Patients with chronic lymphocytic leukemia, Hodgkin's disease, breast and lung cancer (both small and non-small cell) are potential candidates for this study after they have developed progressive disease on SWOG protocols of higher priority. They must have a life expectancy of at least 6 weeks and a Performance Status of 0-3. Measurable disease is desirable but not required.

It is estimated that 30 patients in each category will need to be entered in order to have 25 patients which are response-evaluable.

Therapy will follow the schema outlined in the study protocol.

Progress: A good response to colchicine has been noted in small cell lung cancer.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: SWOG 7963	Status: Ongoing

TITLE:

m-AMSA in Melanoma, Myeloma, Lymphoma, Oat Cell Lung and Breast Carcinomas

Start Date: 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: m-AMSA		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy of m-AMSA at a dose of 120 mg/M^2 IV every 3 weeks in producing regressions or remission in metastatic melanoma, lymphoma, myeloma, metastatic oat cell lung carcinoma, and metastatic breast cancer, which are resistant to standard chemotherapies.

To determine the effect of m-AMSA on survival of patients with metastatic melanoma, lymphoma, myeloma, metastatic oat cell carcinoma of the lung, and metastatic breast cancer, which are resistant to standard chemotherapies.

To correlate in vitro m-AMSA sensitivities in the tumor stem cell colony drug system and in vivo m-AMSA activity in patients with metastatic melanoma, lymphoma, myeloma, metastatic oat cell carcinoma of the lung and metastatic breast cancer, all of which are resistant to standard chemotherapies.

Technical Approach: Patients must have histologically confirmed melanoma, myeloma, breast carcinoma, lymphoma or oat cell carcinoma of the lung, refractory to standard therapies. Patients must have measurable disease and a life expectancy of six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There were 66 breast patients entered in this broad Phase II pilot; of these, 30 are presently response evaluable resulting in 3 PR's and 5 disease improvements.

Minimal response has been seen in oat cell carcinoma with 12 patients having progression of disease and 2 with an improvement in disease status.

Thirteen evaluable melanoma patients have been entered on this study, all having been pre-treated. One PR has been reported, and 1 patient had less than a partial response, giving this agent a 5-10% response rate. Of these pre-treated patients, 10% are sensitive in vitro to m-AMSA, while a 26% sensitivity rate has been reported in patients who have not received prior chemotherapy.

SWOG 7963 (continued)

To date there are 7 evaluable patients. More data will be required before any conclusions can be made.

The study has been closed to lymphoma and breast cancer patients.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7965	Status: Ongoing

TITLE: Treatment of Early Squamous Cell Carcinoma of the Head and Neck with Initial Surgery and/or Radiotherapy Followed by Chemotherapy vs No Further Treatment, Phase III.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Squamous cell carcinoma of head and neck Radiotherapy Chemotherapy	
Accumulative MEDCASE Cost: / Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine if the disease-free interval and survival of patients in high risk categories of squamous head and neck cancer can be improved by adjuvant methotrexate after initial surgery, radiotherapy or both have resulted in no clinically evident disease.

Technical Approach: Patients with histologically proven squamous cell carcinoma of the head and neck who have been rendered clincally disease free by s surgery or radiotherapy are eligible. Patients must be entered within three months of completion of radiotherapy or surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: Thus far there are 8 evaluable patients on the "no treatment" arm and 2 evaluable patients on the MTX arm. No data are available at this time.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7969	Status: Ongoing

TITLE:

Hepatic Infusion and Systemic Combination Chemotherapy in the Treatment of Unresectable Hepatoma, Phase II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Hepatoma, unresectable Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the remission rate seen with induction chemotherapy consisting of intra-arterially infused 5-FUDR, Adriamycin and Streptozotocin in patients with hepatocellular carcinoma.

Technical Approach: Patients with a histologically confirmed diagnosis of unresectable hepatocellular carcinoma which is localized to the liver are eligible. Patients with local extension of tumor into contiguous organs are eligible. Patients must not have received prior chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual is very slow. Since there has been no untoward toxicity in the patients treated thus far, the study was opened for Group participation.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7980	Status: Ongoing

TITLE:

Study of Cis-Platinum for Recurrent Gliomas.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Gliomas, recurrent Cis-Platinum		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy of the chemotherapeutic agent cis-diammine dichloroplatinum (DDP) in the treatment of gliomas recurrent after prior therapy with irradiation (plus or minus chemotherapy).

To determine the duration of response and survival of patients receiving this therapy.

Technical Approach: All patients with gliomas (grade I-IV) who have recurred following cranial irradiation will be eligible. It is essential that patients have evaluable lesions on either CT or radionuclide brain scan.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirteen patients have been entered on this study, with 12 patients still too early to evaluate.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7982	Status: Completed

TITLE:

Chlorozotocin in the Treatment of Advanced Sarcomas.

Start Date: FY 80		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Sarcomas Chlorozotocin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine whether chlorozotocin in a dose of 120 mg/M^2 has significant activity in sarcomas by determination of response rate and duration.

To describe toxicities of chlorozotocin not yet defined.

Technical Appraoch: Eligible patients must have biopsy proven advanced bony or soft tissue sarcoma. Patients must have measurable disease and an expected survival of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Forty-one patients have been entered on this study. There have been no significant responses.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7983	Status: Ongoing

TITLE:

Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Grade I and II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A.Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Glioma Radiation therapy CCNU		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone versus radiation and CCNU.

To compare the effectiveness of radiation therapy versus radiation therapy plus CCNU for remission induction and duration of remission.

Technical Approach: Patients with histologically confirmed primary brain tumors of the following histologic types are eligible: Astrocytoma, GradeI and II with incomplete tumor resection. Patients who have had surgery with histologic diagnosis within the previous six weeks are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Eighteen patients have been entered on this study with 15 still too early to evaluate.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: SWOG 7984	Status: Ongoing

TITLE:

Treatment of Chronic Stage CML with Pulse, Intermittent Busulfan Therapy with or without Oral Vitamin-A, Phase III

Start Date: Nov 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Leukemia Busulfan Vitamin A		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of standard pulse, intermittent busulfan therapy plus oral vitamin A in prolonging the chronic phase of CML, and hence in prolonging survival.

Technical Approach: All patients with newly diagnosed chronic stage CML will be eligible for entry onto protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7985	Status: Ongoing

TITLE:

Combined Modality Treatment for ER- Breast Cancer, Phase III.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D.
Key Words: Breast cancer Estrogen receptor negative (Er-)		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare disease-free interval and survival among control group Stage I (and Stage II node negative) breast cancer patients who tumors are determined to be ER- at the time of mastectomy, versus Stage I (and Stage II node negative) ER- patients treated with adjuvant CMFV for 6 months.

To document recurrence patterns among untreated patients with Stage I breast cancer whose tumors are determined to be ER- at the time of mastectomy.

Technical Approach: All female patients having had a radical, modified radical or total mastectomy, or segmental mastectomy with axillary node dissection for potentially curable, histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is less than 10 femtomoles/mg cytosol protein are eligible for this study. Patients must be registered within 28 days of mastectomy. Patients with previous oophorectomy are eligible provided the oophorectomy was not performed for tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was modified to an intermittent drug regimen to be given for six months - Cytoxan, 5-FU, Methotrexate, Vincristine vs no further treatment until relapse. Patient accrual has been slow, and no data are available for analysis at this time.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 7990	Status: Ongoing

TITLE:

Testicular Cancer Intergroup Study.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Testicular cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the disease-free survival and overall survival for surgery alone (with chemotherapy for relapsers) vs surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular cancer.

To register and follow patients with non-seminoma, non-choriocarcinoma stage I testicular cancer, to define prognostic variables which may predict recurrence in this stage group.

To define the difference in disease-free rates and patterns of recurrence based upon histologic subtypes and extent of disease on initial presentation.

To evaluate the role of marker substances such as human chorionic gonadotropin, alpha-fetoprotein and lactic dehydrogenase in the early detection and management of recurrences in patients with stage I and stage II testicular carcinoma.

To evaluate the accuracy of lymphangiogram, CAT scans and ultrasound studies for staging of retroperitoneal nodal involvement.

Technical Approach: Patients with histologically confirmed carcinoma of the testis, stage I or stage II, are eligible. Patients should enter the study between two and four weeks after lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: The Southwest Oncology Group has entered 8 patients in this intergroup study. Insufficient data have been collected for reporting purposes.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 8001	Status: Ongoing

TITLE:

Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Acute lymphoblastic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate the effectiveness as determined by the complete remission rate of the L10 protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL.

To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL.

To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: A) Absolute infiltration of the marrow with >50% blasts; b) Absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100; B) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required.

Therapy will follow the schema outlined in the study protocol.

Progress: Twelve patients have been entered, and it is too early for a comprehensive analysis. However, on patients with adequate data, there have been 8/9 complete responses. Because of poor patient accrual, it was decided to stop the randomization on the maintenance phase. Therefore Arm 1, the POMP-COAP-OPAL therapy will be closed and all patients will now receive the L10 cyclic therapy.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 8003	Status: Completed

TITLE:

Evaluation of MGBG in Non-Oat Cell Cancer of the Lung, Phase II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Non-Oat cell cancer of lung MGBG		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and remission duration with weekly intravenous therapy using MGBG in patients with non-oat cell carcinoma of the lung who have failed on higher priority treatment protocols.

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced metastatic non-oat cell carcinoma of the lung are eligible. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocl.

Progress: The median overall survival for all evaluable patients is 16 weeks. The comparison among three cell types does not show any significant differences.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 8004	Status: Ongoing

TITLE:

Evaluation of DHAD in Soft Tissue and Bone Sarcomas, Phase II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Sarcoma, soft tissue and bone DHAD		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy, by response rate, of Dihydroxyantracenedione (DHAD) in patients with soft tissue and bone sarcomas, who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug used in a single dose every three-week schedule.

Technical Approach: All patients must have histologically proven, incurable soft tissue or bone sarcomas, not eligible for higher priority SWOG studies, in order to be eligible for study. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty seven patients have been accrued so far; however, most of them are too early to be evaluated.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: SWOG 8005	Status: Ongoing

TITLE:

Evaluation of DHAD in Refractory Malignant Lymphomas, Phase II - Pilot

Start Date: 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Ongoing		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: DHAD Malignant melanoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine response-rate and response duration of patients with refractory malignant lumphomas, both Hodgkin's disease and non-Hodgkin's lymphoma treated with anthracenedione used in a single dose every three-week schecule.

To define the qualitative and quantitative toxicities of anthracenedione in a Phase II study.

Technical Approach: All patients with malignant lymphoma who are not eligible for higher priority SWOG protocols are eligible. There are no age restrictions and patients must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The Phase I data indicates a potentially very active agent in refractory malignant lymphoma patients. Thus far there has been one partial response in the two evaluable cases on study.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: SWOG 8006	Status: Ongoing

TITLE: Postoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx, or Larynx, Phase III

Start Date: Nov 80		Est Comp Date: Ongoing
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Epidermoid carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the length of remission, recurrence-rates, survival-rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs. combined therapy utilizing preoperative chemotherapy, surgery and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and post-operative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive 3 courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine and bleomycin.

Progress: This is a new study.

Detail Summary Sheet

Date: 226 Oct 81	Proj No: SWOG 8008	Status: Ongoing

TITLE:

Evaluation of Dihydroxyantracenedione (DHAD) in Refractory Breast Cancer, Phase II.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Breast cancer Dehydroxyanthracenedione (DHAD)	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate and remission duration of refractory breast cancer in patients treated with antracenedione used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of breast cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Ninety-seven patients have been entered to date. However, there is no response data available at this time.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 8009	Status: Ongoing

TITLE:

Evaluation of DHAD in Patients with Refractory Small Cell Lung Cancer, Phase II.

Start Date: FY 80		Est Comp Date: Ongoing
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Small cell lung cancer DHAD		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate and remission duration of refractory small cell lung cancer in patients treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of small cell lung cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: No responses have been seen in the 12 evaluable patients to date. This agent seemed to be well tolerated with minimal activity. It was felt that it would be worthwhile to investigate this agent in patients with no prior Adriamycin.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 8010	Status: Ongoing

TITLE:

Evaluation of DHAD in Advanced Prostate Cancer, Phase II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Prostate cancer DHAD		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate and remission duration in patients with prostate cancer treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of prostate cancer. All patients must have measurable or evaluable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Eight patients have been entered to date; it is too early for analysis at this time.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 8011	Status: Ongoing

TITLE:

Evaluation of DHAD in Patients with Advanced Renal Cell Carcinoma, Phase II.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Renal cell carcinoma DHAD	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate and duration of response in patients with advanced renal cell carcinoma treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II Study.

Technical Approach: All patients with advanced renal cell carcinoma not eligible for higher priority protocols are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the scheme outlined in the study protocol.

Progress: Thirty-eight patients have been entered, all of which are too early to evaluate.

Detail Summary Sheet

Date: 28 Oct 81	Proj No: SWOG 8012	Status: Ongoing

TITLE:

Treatment for Advanced Adenocarcinoma and Large Cell Carcinoma of the Lung: FOMi vs CAP vs FOMi/CAP, Phase III

Start Date: Jan 82		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D. COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Lung Adenocarcinoma Large cell carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate by pairwise comparison the response-rate, duration of response and survival of 3 regimens FOMi, CAP and FOMi/CAP in patients with advanced (TMN Stage III M_1) adenocarcinoma and large cell undifferentiated carcinoma of the lung.

To evaluate the degree of non-cross resistance of FOMi in CAP failures and of CAP on FOMi failures.

To compare the toxicities and side effects of FOMi and CAP.

Technical Approach: Patients are eligible who have a histologically confirmed diagnosis of adenocarcinoma of the lung or large cell undifferentiated carcinoma of the lung. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Patients who fail FOMi or CAP are crossed over to the third arm - FOMi/CAP and are analyzed separately. No unusual problems or toxicities have been reported.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: SWOG 8014	Status: Ongoing

TITLE:

Colchicine in Refractory Chronic Lymphocytic Leukemia, Phase I-II.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chronic lymphocytic leukemia Colchicine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the maximum dose of colchicine that may safely be administered on a once weekly basis.

To determine the response rate standard error (+/- 10%) in patients with chronic lymphocytic leukemia.

To determine quantitative and qualitative toxicity of the drug colchicine administered on a once weekly basis.

Technical Approach: Patients with chronic lymphocytic leukemia who have demonstrated progressive disease on studies of higher priority are eligible. Patients must have recovered from toxicities resulting from prior treatment before the initiation of treatment with colchicine.

Therapy will follow the schema outlined in the study protocol.

Progress: Eleven patients have been entered. Seven are evaluable and showed no response.

Detail Summary Sheet

Date: 28 Oct 81 Proj No: SWOG 8015 Status: Ongoing	
TITLE: Evaluation of Two Combination Chemotherapy Programs, Adriamycin and Cis-Platinum (AP) vs Adriamycin, Cis-platinum plus VP-16 (VAP), in the Treatment of Extensive Squamous Cell Carcinoma of the Lung, Phase III	
Start Date: Jan 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Lung Squamous cell carcinoma	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the activity, in terms of response-rate, remission duration, and survival in patients with extensive squamous cell (epidermoid) carcinoma of the lung, for two combination chemotherapy programs: Adriamycin and Cis-platinum vs VP-16, Adriamycin and Cis-platinum.

To evaluate the relative toxicities of these respective regimens.

To assess the feasibility and reliance of applying "measurable versus evaluable" criteria of tumor regression in determining therapeutical response.

To correlate tumor grade with response and survival.

Technical Approach: Eligible patients are those with "extensive" squamous cell (epidermoid) lung carcinoma defined as "spread beyond the hemithorax and ipsilateral scalene, supraclavicular and mediastinal lymph nodes", equivalent with TNM system Stage III class M_1 with any T or N other than mediastinal, supraclavicular scalene nodes involved. Relapsing or recurrent TNM Stage I or II patients, failing after radiation therapy alone to the primary site of involvement are also eligible for study.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, and it is too early to give an evaluation at this time.

Detail Summary Sheet

Date: 28 Oct 81	Proj No: SWOG 8017	Status: Ongoing

TITLE:

5-FU, Adriamycin, Streptozotocin and Cyclophosphamide (FAC-S) in the Treatment of Metastatic Carcinoid Tumors, Phase II

Start Date: Nov 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Carcinoid		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine whether combination chemotherapy employing 5-FU, Cyclophosphamide, Adriamycin and Streptozotocin is effective in the management of metastatic carcinoid.

To study the duration of survival of patients with metastatic carcinoid tumor treated with combination chemotherapy regimens.

To provide further information concerning the response and/or survival of patients with metastatic carcinoid originating in different sites and having different metastatic patterns.

Clinical Approach: All patients must have biopsy-proven carcinoid tumor not amenable to further surgical therapy with no prior chemotherapy. A minimum life expectance of 6 weeks and a performance status of 3 or better per Southwest Oncology Group criteria is necessary. All patients must have objectively measurable disease either as a measurable lesion or significant biochemical abnormality specific for their tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 28 Oct 81	Proj No: SWOG 8020	Status: Ongoing

TITLE:

Adriamycin + VP-16 vs Adriamycin Alone in Advanced Adenocarcinoma of the Breast, Phase II

Start Date: Jan 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Adenocarcinoma Breast		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy of the Adriamycin and VP-16 combination in the treatment of previously treated patients with disseminated breast cancer, as determined by response-rate compared with Adriamycin alone.

To determine the length of the remission on VP-16 maintenance after an Adriamycin/VP-16 regimen.

Technical Approach: Patients must have histological proof of breast cancer currently Stage IV with measurable lesions. ER+, ER-, and ER unknown patients are eligible. Patient must have adequate cardiac function and no clinical evidence of congestive heart failure.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has only 4 patients entered to date and they are too early for analysis.

Detail Summary Sheet

Date: 28 Oct 81	Proj No: SWOG 8024	Status: Ongoing

TITLE:

Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase III

Start Date: May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC
Key Words: Sarcoma		John D. Cowan, M.D., MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the effectiveness of bolus administration of Adriamycin and DTIC, to continuous infusion administration of Adriamycin and DTIC, in remission induction of patients with disseminated soft tissue sarcomas.

To compare the toxicities of these two drug schedules.

To determine the feasibility on a group-wide basis of surgical excision of accessible lesions in partially responding patients.

To compare the histology of the diagnostic lesion with the histology of tumor removed from the partial responder.

Technical Approach: Patients with a biopsy confirmed diagnosis of a soft tissue sarcoma with convincing clinical or biopsy-documented evidence of metastatic disease are eligible for this study. Patients must not have received any prior chemotherapy with the agents used in this study. Patients must have a life expectancy of 10 weeks, and all patients must have lesion(s) which is measurable and can be followed for tumor response.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 28 Oct 81	Proj No: SWOG 8025	Status: Ongoing

TITLE:

Combination Chemotherapy for Chronic Lymphocytic Leukemia

Start Date: 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chronic lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and duration of remission in patients with CLL treated with combination chemotherapy consisting of Prednisone, Vincristine, Cytosine Arabinoside, Cytoxan, and Adriamycin.

To correlate parameters obtained in the clinical, pathological, and immunological staging with response to treatment.

To determine the effect of stopping chemotherapy after patients have achieved a complete remission plus two consolidation courses, in order to define a cured or stabilized fraction of patients.

Technical Approach: All patients who fulfill the criteria for diagnosis of chronic lymphocytic leukemia according to the Rai Classification will be eligible for registration.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-six patients have been registered, most of whom are too early to evaluate. Evidence so far suggests that this regimen is equal to the CAP regimen. Combination chemotherapy appears to be more effective than single-agent therapy.

Detail Summary Sheet

Date: 28 Oct 81	Proj No: SWOG 8026	Status: Ongoing

TITLE:

Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the Penis, Phase II

Start Date: Jan 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Epidermoid carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine response-rate and survival in patients with advanced epidermoid carcinoma of the penis treated with Cis-platinum.

Technical Approach: Patients must have epidermoid carcinoma of the penis confirmed by biopsy, Stage III or IV, refractory to surgery and radiotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered, both of which showed a partial response.

Detail Summary Sheet

Date: 28 Oct 81		Proj No: SWOG 8027	Status: Ongoing

TITLE:

The Natural History of Pathological Stage T_{1-2} N_0 M_0 ER+ Breast Cancer, Phase III

Start Date: 11 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Breast cancer	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To document recurrence-rates, patterns of recurrence, and survival among patients with Stage I or Stage II node negative (T_{1-2} N_0 M_0) breast cancer whose tumors are determined to be estrogen receptor positive at the time of surgery.

Technical Approach: All female patients having had a radical, modified radical, or adequate local excision, with axillary node dissection for histologically proven breast carcinom, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is positive are eligible for this study.

Progress: This is a new study; no reportable data are available at this time.

Detail Summary Sheet

Date: 28 Oct 81	Proj No: SWOG 8028	Status: Ongoing

TITLE:

Evaluation of DHAD in Gynecologic Cancers, Stage II

Start Date: 11 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Gynecologic cancer	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and remission duration in patients with gynecologic tumors treated with DHAD used in a single dose every-three-week schedule.

To define the qualitative and quantitative toxicities of DHAD as administered in this Phase II Study.

Technical Approach: To be eligible for this study, patients must have a pathologically verified histologic diagnosis of ovarian (epithelial type), endometrial, or cervical (squamous cell type) carcinoma. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8030	Status: Ongoing

TITLE:

Evaluation of DHAD in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase II

Start Date: 11 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Squamous cell carcinoma	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and remission duration in patients with advanced squamous cell carcinoma of the head and neck treated with DHAD used in a single dose every-three-week schedule.

To define further the qualitative and quantitative toxicities of DHAD.

Technical Approach: To be eligible for this study, patients must have a verified histologic diagnosis of squamous cell carcinoma of the head and neck region. All patients must have a life expectancy of at least three months.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8031	Status: Ongoing

TITLE:
Evaluation of DHAD in Refractory Multiple Myeloma, Phase II

Start Date: 11 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Multiple myeloma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and response duration of patients with refractory multiple myeloma treated with dihydroxyanthracenedione (DHAD) used in a single dose every-three-week schedule.

To define the qualitative and quantitative toxicites of DHAD administered in a Phase II study.

Technical Approach: All patients with multiple myeloma who are not eligible for higher priority Southwest Oncology Group protocols are eligible. Patients must have clearly measurable myeloma protein levels and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was recently activated. Only four patients have been accrued to date. However, preliminary information shows evidence of in vitro activity with this agent in myeloma in the myeloma stem cell assay.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8032	Status: Ongoing

TITLE:

Evaluation of DHAD in Acute Leukemia, Phase II

Start Date: 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Acute leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy of dihydroxyanthracenedione (DHAD) in patients with adult acute leukemia, who have failed on higher priority treatment protocols, as determined by response-rate and remission duration.

To determine the nature and degree of toxicity of this drug used in a single-dose, every-three-week schedule.

Technical Approach: Eligible patients must have a bone marrow diagnosis of acute leukemia.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirteen patients have been registered, but are too early to evaluate.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8033	Status: Ongoing

TITLE:

Trial of m-AMSA in Sarcomas of the Bone and Cartilage, Phase II

Start Date: 11 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Bone sarcoma Cartilage sarcoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of m-AMSA in producint regression or remission in refractory sarcomas arising within the bone or cartilage.

Technical Approach: All patients having histologically proven disease with bony and cartilagenous sarcomas who failed accepted standard intervention with surgery, chemotherapy, and/or radiotherapy are eligible. Patients must have measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has just recently been activated. It is too early for analysis.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8037	Status: Ongoing

TITLE:

Combined Therapies for Squamous Cell Carcinoma of the Esophagus, Phase II

Start Date: 22 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Squamous cell carcinoma	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the feasibility and toxicity of combined radiotherapy and chemotherapy with 5-fluorouracil and cis-platinum followed by surgery in patients with epidermoid carcinoma of the middle or distal esophagus.

To determine the time to local or distant progression in patients treated by these three combined modalities.

To determine the survival of patients treated by these three combined modalities.

To determine the response-rate by clinical and pathological staging at the time of surgery.

Technical Approach: Previously untreated patients with biopsy-proven squamous cell carcinoma of the middle or distal esophagus are eligible. Patients must be judged medically to be a surgical candidate for laparotomy and thoracotomy. Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: Nine patients have completed the study. Five had no cancer in resected specimens. One patient, not really eligible for the study, was treated according to protocol with an increase in radiation dose to 5,000 rads. This patient has a normal barium swallow nine months after treatment.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8038	Status: Ongoing

TITLE:

Vinblastine in Advanced Ovarian Cancer, Phase II

Start Date: 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Ovarian cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and remission duration with intravenous therapy using Velban as a continuous infusion in patients with advanced ovarian cancer.

To define further the qualitative and quantitative toxicity of the continuous infusion of Velban.

Technical Approach: To be eligible, patients must have histologically confirmed, advanced, incurable ovarian cancer who are refractory to or ineligible for treatment on Southwest Oncology Group protocols of higher priority. Patients must have measurable disease and a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is too early for any evaluation at this time.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8040	Status: Ongoing

TITLE:

Evaluation of Combination Chemotherapy (FAM-S) vs a Phase II Drug in Pancreatic Adenocarcinoma, Phase II

Start Date: 22 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Pancreatic adenocarcioma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and survival in patients with advanced pancreatic adenocarcinoma treated with 5-FU, Adriamycin, Mitomycin-C and Streptozotocin (FAM-S).

To determine further the toxicity of the FAM-S regimen.

To determine the activity of a Phase II drug in previously untreated patients with advanced adenocarcinoma of the pancreas by determination of response-rate and duration of response and survival.

To determine further the toxicity of each Phase II agent.

Technical Approach: Patients with histologic confirmation of adenocarcinoma of the exocrine pancreas with distant metastases and/or those with localized disease not amenable to curative surgery or radiotherapy are eligible. All patients must have objectively measurable disease and a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is too early for analysis.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8042	Status: Ongoing

TITLE:

Evaluation of MGBG in Pancreatic Adenocarcinoma, Phase II

Start Date: 22 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John A. Cowan, M.D., MAJ, MC
Key Words: Pancreatic adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and its duration in patients with advanced adenocarcinoma of the pancreas treated with MGBG.

To determine the qualitative and quantitative toxicities of MGBG when given on this schedule.

Technical Approach: Patient eligibility is as stated in SWOG 8040.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8043	Status: Ongoing

TITLE:

Evaluation of DHAD in Pancreatic Adenocarcinoma

Start Date: 22 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Pancreatic adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity of DHAD, as determined by response-rate and duration of response, used in a single dose schedule every three weeks in patients with advanced adenocarcinoma of the pancreas.

To determine additional information concerning the nature and degree of toxicity of this drug.

Technical Approach: Patient eleigibility is as outlined in SWOG 8040. In those patients treated initially on the FAM-S arm, patients must have received no mitomycin-C for 6 weeks; no Adriamycin, 5-FU or streptozotocin for 3 weeks; and must show evidence of hematologic recovery prior to beginning treatment with DHAD.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8051	Status: Ongoing

TITLE:

Evaluation of L-Alanosine in Acute Leukemia, Phase II

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Acute leukemia L-Alanosine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity of L-alanosine as determined by response-rate and duration of response in patients with acute leukemia who are not eligible for higher priority studies.

To determine the nature and degree of toxicity of this drug.

Technical Approach: Patients with acute leukemia, either lymphocytic or non-lymphocytic, not eligible for higher priority Southwest Oncology Group studies are eligible. Patients must have at least a 30% cellular marrow and 30% leukemic cells.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 29 Oct 81 Proj No: SWOG 8066 Status: Ongoing

TITLE: Adjuvant Intrahepatic Chemotherapy with Mitomycin-C and 5-FU Combined with Hepatic Radiation in High Risk Patients with Carcinoma of the Colon, Phase II-Pilot

Start Date: Jan 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Carcinoma of colon	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the toxicities of combined intra-arterial chemotherapy with hepatic radiotherapy in patients after total clinical resection of cancer of the colon who have a high risk of recurrence, for potential use in an adjuvant Group-wide protocol.

Technical Approach: To be eligible, the patient must have adenocarcinoma of the large bowel with involvement of the adjacent regional lymph nodes. There must be no evidence of any residual tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: To date two patients have completed the treatment outlined in the protocol and are disease-free; they did not suffer any acute toxicities from the treatment.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8090	Status: Terminated

TITLE:

A Descriptive Study of Chemotherapy Drug Extravasation and Treatments Commonly Instituted Among the Southwest Oncology Group, Ancillary Study

Start Date: 1 Apr 81		Est Comp Date:
Principal Investigator Rosemary Madden, CPT ANC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators:
Key Words: Ancillary Study		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To provide descriptive information about extravasation of commonly used chemotherapeutic agents in humans, including correlation between local tissue damage and dose of medication, concentration of medication, and factors of patients' physical status.

To provide descriptive information about treatments commonly used in the Southwest Oncology Group for drug extravasation.

Technical Approach: Any male or female adult patient who is receiving intravenous chemotherapy and has evidence of an extravasation is eligible for the study.

Progress: This study was not started due to transfer of principal investigator.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8092	Status: Ongoing

TITLE:

Use of Human Tumor Cloning System to Select Chemotherapy for Patients with Ovarian Cancer Refractory to Primary Therapy, Ancillary Study

Start Date: 11 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Human tumor cloning system	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To utilize the human tumor cloning assay to select single agent chemotherapy for patients with epithelial-type ovarian cancer, refractory to standard therapy.

To determine if the human tumor cloning system can be utilized to select individual patient's therapy in a cooperative group setting.

Technical Approach: Eligible patients must have a pathological diagnosis of epithelial-type ovarian cancer in pleural or peritoneal fluid. Patients should have measurable disease and a life expectancy of at least three months.

Progress: This is a new study.

Detail Summary Sheet

Date: 29 Oct 81	Proj No: SWOG 8094	Status: Ongoing

TITLE:

Radiotherapy with and without Chemotherapy for Malignant Mesothelioma Localized to One Hemithorax, Phase III

Start Date: 22 May 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Periodic Review Results:	Continue

Objectives: To evaluate in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma.

To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

APPENDIX B

GYNECOLOGY ONCOLOGY GROUP

Detail Summary Sheet

Date: 26 Oct 81	Proj No: GOG 20	Status: Ongoing

TITLE: A Randomized Comparison of Adriamycin vs No Further Therapy in Patients with Uterine Sarcomas, Stage I and II, Phase III

Start Date: FY 81	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecoly	Associate Investigators:
Key Words: Uterine Sarcoma Adriamycin	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine if adjuvant chemotherapy will improve the cure rate in uterine sarcomas, Stage I and II.

Technical Approach: Patients with histologically proven sarcomas of the uterine corpus will be considered if they have Stage I or Stage II disease clinically, and if they have no known gross residual disease following surgery. Preoperative or postoperative pelvic radiotherapy may be given at the discretion of the principal investigator, but a decision about this mode of therapy must be made prior to the chemotherapy randomization.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no significant difference in survival and progression-free interval between the two programs. Moreover, Mantel-Haentzel techniques adjusting for such parameters as stage, histology, prior radiotherapy and various combinations of these three have been employed, revealing no treatment difference.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: GOG-24	Status: Ongoing

TITLE: Treatment of Women with Cervical Cancer Stage IIB, IIIB, IVA, Confined to the Pelvis and/or para-aortic nodes with Radiotherapy Alone vs Radiotherapy plus Immunotherapy (Phase II).

Start Date: FY 78	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Cervical cancer Radiotherapy Immunotherapy	
Accumulative MEDCASE Cost: / Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To assess the therapeutic effectiveness of immunotherapy (intravenous C-parvum) used concommitantly with radiation in patients with advanced carcinoma of the uterine cervix.

Technical approach: Patients with histologically confirmed, previously untreated carcinoma of the uterine cervix (adenocarcinoma or squamous carcinoma) are eligible.

Therapy will be in accordance with the schema outlined in the study protocol.

Progress: Preliminar analysis suggests that C-parvum does not add any therapeutic effect as an adjuvant to radiotherapy in this patient population.

Detail Summary Sheet

Date: 26 Oct 81 Proj No: GOG-25 Status: Ongoing	
TITLE: A Randomized Comparison of Melphalan Therapy Alone vs Melphalan plus Immunotherapy (C. Parvum) in the Treatment of Women with Stage III (Optimal) Epithelial Carcinoma of the Ovary (Phase II).	
Start Date: FY 78	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Epithelial carcinoma, ovary Immunotherapy C. Parvum	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of adjuvant nonspecific immunotherapy to standard alkylating agent therapy in patients with Stage III optimal carcinoma of the ovary.

Technical Approach: Patients in "optimal" category (3 cm or less greatest diameter of residual tumor(s) with proven primary Stage III epithelial cancer of the ovary) who have undergone tumor-reductive surgey will be included in the study.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no significant difference when the duragion of progression-free interval and survival are compared by therapy. When progress-free interval and survival are compared by size of residual tumor at surgery, both are highly statistically significant. However, it is too early to draw any conclusions.

Detail Summary Sheet

Date: 26 Oct 81	Proj No: GOG-26	Status: Ongoing

TITLE:

Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies.

Start Date: FY 78		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Pelvic malignancies Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol. Agents to be used in this study include: Piperazinedione, Cis-platinum, VP-16, Galacticol, Baker's Antifol, ICRF-159, Maytansine, m-AMSA and Yoshi 864.

Progress: Cis-platinum has marked activity as first line chemotherapy of squamous cell carcinoma of the cervix and is active as second line therapy of advanced ovarian carcinoma at the dose and schedule tested. The drugs appears to be inactive against endometrial carcinoma but may have limited activity in the therapy of sarcomas and cervical adenocarcinomas.

Because of the demonstrated activity of Cis-platinum in squamous cell carcinoma of the cervix, a phase III study comparing three different regimens of Cis-platinum in advanced squamous cell carcinoma of the cervix was activated as GOG 43.

GOG 26 (continued)

Because of the demonstrated activity of Cis-platinum in epithelial ovarian carcinoma, protocol GOG 47 was activated comparing Adrimycin plus Cyclophosphamide plus Cis-platinum with Adriamycin plus Cyclophosphamide.

VP-16 - VP-16 appears to have minimal activity against ovarian adenocarcinoma and insignificant activity against squamous cell carcinoma of the cervix at the dose and schedule tested.

Galacticol - Complete and partial remissions in carcinoma of the cervix have been 19% which is encouraging enough for future studies, possibly in combination with other drugs. One complete remission continues at 33+ months.

Complete and partial remissions in carcinoma of the ovary were 15%. Almost all of these patients had received prior chemotherapy. One complete remission continues at 24+ months; the other relapsed 15 months after entry.

Baker's Antifol - Although limited activity is noted, this drug is not as useful as more conventional drugs and probably will not add to current therapeutic regimens.

IRCF - IRCF appears to have moderate activity in squamous cell carcinoma of the cervix at the dose and schedule tested despite induction of significant myelosuppression. Results of this study will be used to determine the future role, if any, of ICRF-159 in the treatment of gynecologic cancer either alone or in combination with other drugs.

AMSA and YOSHI - It is too early to evaluate the results. When these are obtained, they will be used to determine the future role, if any of AMSA and YOSHI in the treatment of gynecologic cancer either alone or in combination with other drugs.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 31	Status: Ongoing

TITLE:

A Randomized Comparison of Local Excision vs Cryosurgery in Patients with Limited Grade 1, 2, or 3 Cervical Intraepithelial Neoplasia.

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Cervical neoplasia Cryosurgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate and compare the immediate and long-term effectiveness of outpatient cryosurgery and outpatient local excision in the treatment of limited cervical intraepithelial neoplasia grade 1, 2 or 3, in a randomized prospective study.

Technical Approach: All eligible patients must have a tissue diagnosis of cervical intraepithelial neoplasia within six weeks prior to randomization in the study. All patients must have a lesion which can be completely delineated through the colposcope. Only patients with the following histologic diagnosis will be eligible: mild dysplasia, moderate dysplasia, severe dysplasia, and carcinoma in situ.

Therapy and randomization will follow the schema outlined in the study protocol.

Progress: Median follow-up for the evaluable patients on this study is only 13.5 months; consequently, it is still too early to perform a meaningful analysis.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 32	Status: Ongoing

TITLE:

A Radomized Comparison of Surgical Conization vs Cryosurgery in Patients with Extensive Grade 3 Cervical Intraepithelial Neoplasia.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Cervical neoplasia Cryosurgery	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate and compare the immediate and long-term effectiveness of outpatient cryosurgery to the standard cold-knife conization in the treatment of extensive cervical intraepithelial neoplasia Grade 3 in a randomized prospective study.

Technical Approach: All eligible patients must have a diagnosis of cervical intraepithelial neoplasia within six weeks prior to randomization in the study. All patients must have a lesion which can be completely delineated through the colposcope. The lesion should involve at least two quadrants of the portio. Only patients with the following histologic diagnosis will be eligible: severe dysplasia and carcinoma in situ.

Therapy and randomization will follow the schema outlined in the study protocol.

Progress: It is too early to draw comclusions. The protocol has been modified to allow more time (12 weeks) from tissue diagnosis to entry into protocol.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 33	Status: Completed

TITLE:

A Clinical-Pathologic Study of Stage I and II Carcinoma of the Endometrium.

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Endometrial carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the incidence of pelvic and aortic lymph node metastases and the relationship of these node metastases to other important prognostic factors.

Technical Approach: All patients with histologically proven endometrial carcinoma clinical FIGO Stage I and II who are medically suitable for hysterectomy and lymphadenctomy are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Preliminary evaluation would tend to indicate that this larger study verifies the findings of the pilot study. It would appear that this study could define the surgical procedure required for optimal evaluation of endometrial cancer.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 34	Status: Ongoing
TITLE: A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I, and Occult Stage II.		
Start Date: FY 78		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Endometrial carcinoma Radiation therapy Adriamycin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To study differences in morbidity and patient survival as functions of various tumor growth patterns as well as treatments.

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the endometrium Stage I, and Stage II occult, all grades, with one or more of the following high risk criteria are eligible: (1) all lesions with equal to or greater than one-half myometrial involvement; (2) positive pelvic and/or para-aortic nodes; (3) microscopic evidence of cervical involvement but no gross clinical involvement of the cervix. The following types of histologically confirmed uterine carcinoma are eligible: adenocarcinoma, adenoacanthoma, adenosquamous carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to draw any meaningful conclusions from the data available.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 36	Status: Ongoing

TITLE:

Surgical-Pathologic Study of Women with Squamous Cell Carcinoma of the Vulva.

Start Date: FY 78	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Squamous cell carcinoma of vulva	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor in millimeters, histologic grade, and site and number of positive lymph nodes in Stage I-IV carcinoma of the vulva.

To rapidly accumulate prospectively significant surgical pathologic data for development of further protocols for subsets of disease identified.

To determine morbidity of primary radical surgical therapy.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the vulva clinically determined to be Stage I through IV are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to evaluate the data obtained from this study.

Detail Summary Sheet

Date: 27 Oct 81 Proj No: GOG 37 Status: Ongoing

TITLE: Randomized Study of Radiation Therapy vs Pelvic Node Resection for Patients with Invasive Squamous Cell Carcinoma of the Vulva Having Positive Groin Nodes.

Start Date: FY 78	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Squamous cell carcinoma of vulva	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the benefit and morbidity of adding adjunctive radiation therapy to pelvis and groin for patients with positive groin nodes at radical vulvectomy and bilateral groin dissection.

Technical Approach: All patients with primary, previously untreated, histologically confirmed squamous cell carcinoma of the vulva such that radical vulvectomy suffices to remove all of the local lesion and whose surgery revealed that there were nodes in the groin on one or both sides containing metastatic carcinoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOC 40	Status: Ongoing

TITLE:

A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas.

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Uterine sarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the incidence of pelvic and aortic lymph node metastases associated with Stage I and II uterine sarcomas, the relationship of these node metastases to other important prognostic factors such as mitotic index of the tumor, and the complication rate of the procedures.

Technical Approach: All patients with histologically proven uterine sarcoma clinical Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early for meaningful analysis of data.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 41	Status: Ongoing

TITLE:

Surgical Staging of Ovarian Carcinoma.

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Ovarian carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the spread of ovarian carcinoma in intraperitoneal structures and retroperitoneal lymph nodes by direct examination, cytologic sampling, and biopsy.

To establish a surgical protocol for patients entered into GOG ovarian cancer treatment protocols.

To determine the complication rate of the procedures.

Technical Approach: Patients with all histologic types of primary ovarian cancer are eligible, including epithelial tumors, germ cell tumors, stromal tumors, and all others. Patients must be entered within two weeks of the last surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: There are presently insufficient data to permit a detailed analysis. Initial results indicate a good correlation between reported stage and surgical stage for stage I, II and III patients.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 42	Status: Ongoing

TITLE:

Treatment of Recurrent or Advanced Uterine Sarcoma. A Randomized Comparison of Adriamycin vs Adriamycin and Cyclophosphamide, Phase III.

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Uterine sarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine if Adriamycin alone is more effective than Adriamycin and Cyclphosphamide in producing responses in advanced or recurrent uterine sarcoma.

To determine the duration of response for each different treatment arm.

Technical Approach: Patients with primary Stage III, primary Stage IV or recurrent uterine sarcoma are eligible. Both patients with measurable and non-measurable disease are eligible, but they will be analyzed separately. Patients with all cell types of uterine sarcoma are eligible.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: Thirty-three patients have measurable disease. To date, there has been 1 complete response, 5 partial responses, 9 progressions and 18 with stable disease. The regimens are well tolerated.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: COG 43	Status: Ongoing

TITLE: A Randomized Comparison of Cis-platinum 50mg/m2 IV Every 3 weeks vs Cis-platinum 100mg/m2 IV Every 3 weeks vs Cis-platinum 20mg/m2 IV Daily x 5 Days in Treatment of Patients with Advanced Carcinoma of the Cervix, Phase III.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Carcinoma of cervix	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To confirm the effectiveneass of cis-diamminedichloroplatinum (DDP) in advanced and recurrent squamous cell carcinoma of the cervix no longer responding to radiation therapy or surgery.

To compare the frequency and duration of response and adverse effects of DDP therapy using three different doses and treatment schedules.

To evaluate the roles of serial determination of serum carcinoembryonic antigen (CEA) levels in determining extent of disease, response to treatment, and in predicting treatment failure.

Technical Approach: Eligible patients must have histologically confirmed, locally advanced, recurrent, persistent, or metastatic squamous cell carcinoma of the cervix which is resistent to curative treatment with surgery or radiotherapy. All patients must have lesions which are measurable or evaluable by physical examination. Patients will have recovered from effects of recent surgery or radiotherapy, and will be free of clinically significant infection.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: There is no significant difference in response when the three regimens are compared. Median time to response for regimens A, B and C is 2.5, 1.9 and 2.4 months, respectively. Survival by response category shows a significant difference at the .001 level.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 44	Status: Ongoing

TITLE: Evaluation of Adjuvant Vincristine, Dactinomycin, and Cyclophosphamide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of All Gross Tumor, Phase III.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Germ cell tumor of ovary	
Accumulative MEDCASE Cost: / Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate the effect of combined prophylactic vincristine, dactinomycin, and cyclophosphamide chemotherapy in patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (Grades 2 and 3), choriocarcinoma, and malignant mixed germ cell tumors of the ovary, Stages I and II after total removal of all gross tumor.

To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta HCG), when these are present, in predicting response and relapse.

To determine the role of restaging laparotomy in determining response, predicting relapse and planning further therapy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary, Stages I or II, if previously untreated and completely resected, excluding patients with pure dysgerminoma unless classified as anaplastic, are eligible. Patients with grade 2 or 3 immature teratoma are also eligible. Patients with early Stage III disease will be accepted if all gross tumor is resected.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: Twenty-two patients have had second-look operations performed; 16 were negative, four were positive, and two had mature teratoma. Of the five positive second-looks, two had endodermal sinus tumors, one had embryonal carcinoma, and one had a mixture of rare ovarian components. In addition to these four, there are four other failure, three of whom had had negative second-look operations. All patients are alive.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 45	Status: Ongoing

TITLE:

Evaluation of Vinblastine, Bleomycin, and Cis-platinum in Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary, Phase III.

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Malignant germ cell tumor of ovary		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate the effect of four cycles of combined Vinblastine, Bleomycin and Cis-platinum (VBP) chemotherapy in the management of patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (all grades), choriocarcinoma, and malignant germ cell tumors of the ovary with advanced or recurrent disease, incompletely resected.

To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta HCG), when these are present, in predicting response and relapse.

To determine the role of restaging laparotomy in patients in clinical remission, in assessing completeness of response, and in planning further therapy.

To evaluate and compare the effect of Vincristine, Dactinomycin and Cyclophosphamide (VAC) chemotherapy in patients found to have persistent disease at the time of restaging laparotomy.

To determine the need for maintenance Vinblastine therapy in patients free of disease at restaging laparotomy.

Clinical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary with advanced (Stage III-IV) or recurrent disease, incompletely resected, excluding patients with pure dysgerminoma (mature or anaplastic) are eligible. Patients with incompletely resected Stage II disease and patients previously treated with Vincristine, Dactinomycin and Cyclophosphamide are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There continues to be considerable toxicity; however, early results are encouraging.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 46	Status: Ongoing
TITLE: A Randomized Comparison of Melphalan vs Intraperitoneal Chromic Phosphate in the Treatment of Women with Stage I (exclusive of Stage IA(1) G1 and IB(i) G1) Epithelial Carcinoma of the Ovary, Phase III.		
Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Epithelial carcinoma of ovary		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate the relative effectiveness of Melphalan vs intraperitoneal Chromic Phosphate as adjuvant therapy in Stage I exclusive of Stage IA (i) G1 and Stage IB(i) G1 epithelial cancers of the ovary in a randomized prospective study.

Technical Approach: Patients with surgical Stage IA(i) Gs, G3; IA(ii); IB(i) G2, G3; IB(ii), and IC epithelial cancer of the ovary who have undergone optimal staging described in GOG 41 are eligible.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: It is too early to draw any conclusions.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 47	Status: Ongoing
TITLE: A Randomized Study of Adriamycin + Cyclophosphamide vs Adriamycin + Cyclophosphamide + Cis-platinum in Patients with Advanced Ovarian Adenocarcinoma - Suboptimal Stage II, Stage IV and Recurrent, Phase III.		
Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Ovarian adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine if the addition of Cis-platinum to Adriamycin plus Cyclophosphamide improves remission rate, remission duration or survival in Stage IV, suboptimal Stage III and recurrent ovarian adenocarcinoma.

To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients who have been diagnosed as Stage IV and suboptimal Stage III primary cases together with all recurrent cases are eligible. Both patients with measurable disease and patients without measurable disease, as a separate category, will be evaluated.

Therapy will follow the schema outlined in the study protocol.

Progress: To date, there is no survival difference. The addition of Cis-platinum appears to significantly influence response and progression-free interval but at this relatively early date there are still many censored observations.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 48	Status: Ongoing

TITLE: A Study of Progestin Therapy and A Randomized Comparison of Adriamycin vs Adriamycin + Cyclophosphamide in Patients with Advanced Endometrial Carcinoma After Hormonal Failure, Phase III.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Endometrial Carcinoma	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate the response of advanced or recurrent endometrial carcinoma to oral progestins in patients who have received no prior hormonal therapy.

To compare a combination of adriamycin and cyclophosphamide to adriamycin alone as therapy for advanced or recurrent endometrial carcinoma which no longer responds to or has failed to respond to progestins in patients who have received no prior cytotoxic drugs.

Technical Approach: To be eligible for entry on this study, all patients must have documented primary Stage III, primary Stage IV, recurrent or residual endometrial adenocarcinoma, adenoacanthoma or adenosquamous carcinoma. Those patients with positive cytology as evidence of spread are eligible as non-measurable disease cases.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 27 Oct 81 Proj No: GOG 49 Status: Ongoing

TITLE: A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix Stage IB and Randomly Assigned Radiation Therapy versus no Further Therapy in Selected Patients.

Start Date: FY 81	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Invasive carcinoma Cervix	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine by observations of the 5-year survival and disease-free interval, the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor, in millimeters, histology and grade, growth pattern, and site and number of positive lymph nodes in Stage IB carcinoma of the cervix.

To rapidly accumulate prospectively significant surgical pathologic data which would expedite development of further protocols.

To determine morbidity of primary radical surgical therapy.

To determine if radiation therapy will improve survival in selected patients with positive nodes.

Surgical Approach: All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the cervix (squamous cell, adenocarcinoma or adenosquamous) are eligible. Patients must have had a pelvic and para-aortic lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: GOG 50	Status: Ongoing

TITLE:

A Study of Adriamycin as Postoperative Therapy for Ovarian Sarcoma, Primary or Recurrent, with No Prior Chemotherapy, Phase III.

Start Date: FY 81	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Ovarian sarcoma Adriamycin	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate the efficacy of Adriamycin in the treatment of ovarian sarcomas, primary or recurrent, through historic controls.

To accumulate additional srugical-pathological data relative to ovarian sarcomas.

Technical approach: All patients must have histologically confirmed primary Stage I-IV or recurrent ovarian sarcoma. Optimal reductive surgery is required for cases with advanced disease, whether primary or recurrent. Patients may have measurable disease, non-measurable disease or no residual disease postoperatively. The endometrium must be examined to exclude an endometrial origin of tumor.

Patients with primary Stage I-IV disease must be entered and protocol therapy begun within six weeks of surgery. Patients with recurrent disease must be entered and protocol therapy begun within six weeks of documented recurrence.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 27 Oct 81 Proj No: GOG 51 Status: Ongoing

TITLE: A Randomized Comparison of Droperidol versus THC in the Treatment of Nausea and Vomiting Produced by Cis-platinum Chemotherapy for Gynecologic Malignancies.

Start Date: FY 81	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: THC (Delta-9-Tetrahydrocannabinol) Droperidol (Dehydrobenzperidol) Cis-platinum	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate the effectiveness of Droperidol and THC as anti-emetic agents in chemotherapy of gynecologic malignancies treated with Cis-platinum.

Technical Appraoch: Patients with gynecologic malignancies who receive Cis-platinum as a single agent are eligible. Patients will be randomized to one of two treatment groups. Group 1 will receive THC by mouth during two courses of chemotherapy, and then take droperidol by injection for two chemotherapy courses. Group 2 will receive droperidol by injection for two chemotherapy courses and then THC by mouth during two courses of chemotherapy.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 27 Oct 81	Proj No: 7601	Status: Ongoing

TITLE:

Ovarian Cancer Study Group Protocol for Selected Stage IAi - IBi Ovarian Cancer (Well and Moderately Differentiated).

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: ovarian cancer	
Accumulative MEDCASE Cost: Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To define the natural history (relapse rate, relapse site, relapse free survival) of patients treated by surgery alone.

To determine whether prophylactic, adjuvant chemotherapy with melphalan alters the natural history.

To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

To determine the patterns of relapse for each form of therapy.

To establish the value of various staging parameters on the stage of disease and its natural history.

Technical Approach: All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous, and those listed in Appendix I of the protocol. After definitive staging procedure, if the patient is a selective Stage IAi, or IBi, and the histologic grade is well or moderately differentiated, the patient is eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 27 Oct 81 Proj No: 7602 Status: Ongoing

TITLE:

Ovarian Cancer Study Group Protocol for All Stage IC and II (A,B,C) and Selected Stage IAii and IBii Ovarian Cancer.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator Miltoh H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Ovarian cancer	
[illegible]ative MEDCASE Cost: / Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives; To define the natural history (relapse rate, relapse sites, [illegible]apse free survival, regression rate, duration of regression) of patients [illegible] by surgery plus either chemotherapy or chemotherapy plus radiation therapy.

To study the effect of various potential prognostic factors (stratification factors) on the natural [illegible] of patients [illegible] by each form of [illegible]

[illegible] determine the patterns of relapse for each type of therapy.

To establish the value [illegible] patient [illegible] on the [illegible] and its natural history

[illegible] All [illegible] patients must have a histopathologic diagno[illegible] epithelial [illegible] of one of the following types: serous, [illegible] of the types [illegible] in Appendix [illegible] of the study protocol. [illegible] staging [illegible] if the patient is Stage II-A, II-B, [illegible], I-Bii, or [illegible] with poorly differentiated tumors. She [illegible] this study [illegible] have had no previous treatment [illegible]

[illegible] will follow the schema outlined in the study [illegible]

[illegible] available at this time.

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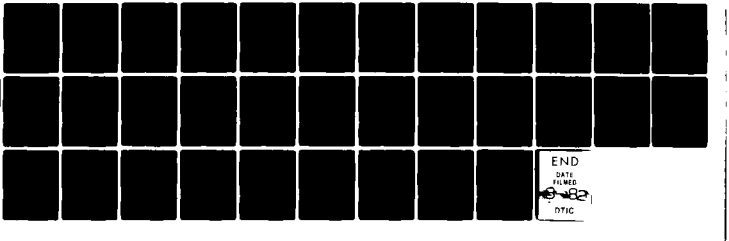

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APPENDIX C

POLYCYTHEMIA VERA STUDY GROUP

Detail Summary Sheet

Date: 13 Oct 81	Proj No: PVSG 5	Status: Terminated

TITLE:

Treatment of Thrombosis in Patients with Polycythemia Vera.

Start Date: FY 79		Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology		Associate Investigators:
Key Words: Thrombosis Polycythemia Vera		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine whether phlebotomy in conjunction with antiaggregating agents can decrease the frequency of thrombotic complications in patients with PV to the level in patients treated with 32P.

Technical Approach: Only those patients who have well-documented, active polycythemia vera, as demonstrated by rigorous diagnostic studies designed to eliminate spurious (stress) polycythemia, anoxic erythrocytosis, or erythrocytosis secondary to increased erythropoietin, or erythrocytosis without additional evidence of myeloproliferative disease either past or present, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: At the Group meeting, March 1981, it was reported that there were 7 thrombotic events in the aspirin/Persantine arm as compared to 2 thrombotic events in the 32-P arm. The one year major thrombotic complication rate on the phlebotomy arm of the study was 8% in comparison to 8.4% on the aspirin/Persantine arm. At the end of two years the major thrombotic incidence rate was equal, being approximately 12%. However, there had been a major increase in the incidence of hemorrhagic events in the aspirin/Persantine arm (6 vs 0). Accordingly, it was recommended that this protocol be closed to patient accrual and that those patients on the aspirin/Persantine arm be treated with phlebotomy alone at the discretion of the individual investigator.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: PVSG 8	Status: Completed

TITLE:

Efficacy Trial Using Hydroxyurea (HU) in Polycythemia Vera.

Start Date: FY 79		Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Polycythemia vera Hydroxyurea		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the efficacy of HU in patients of all ages with polycythemia vera who have active disease and to assess the influence of HU upon the symptoms and signs of active disease and upon the abnormal hematological and biochemical manifestations of the panmyelosis that characterize this condition.

Technical Approach: Only those patients who have well-documented, active polycythemia vera, as demonstrated by rigorous diagnostic studies designed to eliminate spurious (stress) polycythemia, anoxic erythrocytosis, or erythrocytosis secondary to increased erythropoietin, or erythrocytosis without additional evidence of myeloproliferative disease either past or present, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Initial response was evaluated in 88 patients entered in the group-wide study. Two patients who were previously untreated and four patients who were treated had no response to this drug. Of 40 previously untreated patients who had an initial response, response occurred from 5 days to 105 days after therapy was started with a median of 17 days. For the 42 previously treated patients who had initial response, response occurred from 6 days to 130 days with a median of 14.5 days.

The study was closed to patient entry; however, all patients now on hydroxyurea will continue to be followed.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: PVSG-12	Status: Ongoing

TITLE:
Hydroxyurea in Thrombosis.

Start Date: FY 80		Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Thrombocytopenia Myelofibrosis-myeloid metaplasia Myeloproliferative disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the efficacy of hydroxyurea in preventing and controlling the symptoms of thrombosis and bleeding with 1) the clinical entity primary thrombocytopenia, 2) those patients with myelofibrosis-myeloid metaplasia with elevated platelet counts, and 3) those patients with unclassified myeloproliferative disease with elevated platelet counts.

Technical Approach: In order to be eligible for entry on this study, the patient must meet the following criteria: 1) Absence of Philadelphia chromosome, 2) Absence of an increased red cell mass, 3) bone marrow which shows marked megakaryocytic hyperplasia and abundant platelet clumps, 4) Thrombosis not secondary to some identifiable cause, i.e., infection, cancer etc., and 5) Patient must not have had a pre-existing cancer, other than skin cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, there are 41 evaluable patients and 35 of these have achieved a platelet count of $<600,000$, 27 of whom sustained this for a year.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: PVSG-13	Status: Ongoing

TITLE:

Study of the Clinical Features and Natural History of Asymptomatic Patients with Myeloproliferative Disorders.

Start Date: FY 79		Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Myeloproliferative disorder		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To obtain a clinical and laboratory data base on patients with myeloproliferative disorders prior to the time they require treatment under other MPD protocols.

To define the natural course of the disease as to the development of: a) splenomegaly, b) progressive fibrosis, c) leukemic conversion, d) thromboembolic complications, and e) other neoplasm.

To demonstrate the development of cytogenetic and pathologic abnormalities in bone marrow and peripheral blood.

To establish predictors of a more symptomatic stage of the disease.

Technical Approach: All newly diagnosed (less than one year), previously untreated patients (including patients transfused for a period of less than three months) considered to have one of the myeloproliferative disorders outlined in the protocol are eligible.

Progress: Data on all patients entered into the myeloproliferative studies have been transferred to Duke University for evaluation.

Detail Summary Sheet

Date: 22 Oct 81	Proj No: PVSG-15	Status: Ongoing

TITLE:

Efficacy Trial Using Cyproheptadine and Cimetidine for Pruritus in Polycythemia Vera

Start Date: 10 Oct 81		Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology		Associate Investigators:
Key Words: Pruritus Polycythemia Vera		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine whether H_1 and H_2 blocing agents used concomitantly are efficacious in alleviating the pruritus of polycythemia vera.

Technical Approach: Any patient with polycythemia vera in remission, i.e., Hct. of 40-45%, folloiwng treatment who suffers from persistant pruritus which worsens with bathing or showering and which does not antedate the onset of stymptoms of polycythemia vera is eligible for this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual in this study has been slow. However, of those patients entered on the study, the drug combination has been shown to be efficacious in treating pruritus but the number is still too small for a definitive statement.

APPENDIX D

PEDIATRIC ONCOLOGY GROUP

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7376	Status: Ongoing

TITLE:

Evaluation of Natural History of Histiocytosis X in Childhood

Start Date: Feb [illegible]		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Histiocytosis X		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To obtain information about the natural history of all forms of histiocytosis X and histiocytic medullary reticulosis.

Technical Approach: All new patients with a biopsy-proven diagnosis of histiocytosis X should be registered for the study.

This study involves reporting on the results of examinations, tests, and t[illegible]ment during the course of the disease. The examinations and tests are as ou[illegible]lined in the study protocol.

Progress: For patients who developed progressive disease off therapy, the time to appearance of the last new lesion ranged from 2 months to 8 years with a median time of 1 year 8 months and a mean time of 2 years 4 months.

While detailed statistical analyses are not possible at this time, the following has been noted: males dominate the nonprogressive group.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7607B	Status: Completed

TITLE:
AD-CON-FU/Lithium in Children with Metastatic Solid Tumors

Start Date: 25 Sep 81		Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Solid tumors		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the response rates of the combination of AD-CON-FU/Lithium in the treatment of solid tumors in previously treated or untreated children.

Technical Approach: Patients with objectively measurable tumors with epithelial tumors or previously treated sarcomas who are not eligible for other intergroup studies are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been completed prior to approval by the BAMC committees.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7612	Status: Ongoing

TITLE:

MOPP + Bleo vs A-COPP with IF RT in Stage III Hodgkin's Disease in Children

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Hodgkin's disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To compare the effectiveness of IF radiotherapy plus MOPP + Bleo with IF radiotherapy plus A-COPP chemotherapy in treating Stage III Hodgkin's disease in children.

To determine the patient tolerance of the two chemotherapy regimens in terms of immediate toxicity including the incidence of infection.

Technical Approach: All children, 18 years or younger, with Stage III Hodgkin's disease including extranodal presentations + constitutional symptoms, regardless of specific with no prior therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No significant difference ($p = .46$) exists between the two treatment programs when compared by disease-free survival.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7617	Status: Completed

TITLE:

Combination Chemotherapy with Vinblastine Sulfate and Bleomycin Infusion in Children with Metastatic Solid Tumors

Start Date: 25 Sep 81		Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Solid tumors		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate of vinblastine sulfate-bleomycin combination in children with advanced metastatic solid tumors.

To determine the toxicity of this combination in children.

Technical Approach: All children under 18 years of age, previously treated, with recurrent or metastatic solid tumors and Hodgkin's and non-Hodgkin's lymphomas are eligible.

Progress: This study had been completed by the Pediatric Oncology Group prior to BAMC approval. No reportable data are available.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7621	Status: Ongoing

TITLE:

MOPP vs OPP in the Treatment of Children with Recurrent Brain Tumors

Start Date: Feb 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Brain tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine and compare response to MOPP or OPP in children with recurrent brain tumors.

Technical Approach: All patients who have been diagnosed to have a central nervous system tumor, and who have previously received maximally allowable dose of radiotherapy will be eligible for randomization which will require no prior therapy with either nitrogen mustard or BCNU. Patients must be 18 years of age or under at the time of diagnosis.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7623	Status: Completed

TITLE:

Evaluation of Systemic Regimens in the Treatment of Leukemia of Childhood ALinC #12

Start Date: Nov 80		Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the desirability of prospective separation of various prognostic groups among newly diagnosed cases of pediatric lymphocytic leukemia. Within each group variations of treatment regimens are compared with respect to the length of initial remission produced by each.

Technical Approach: Eligible patients must be under 21 years of age and have the diagnosis of ALL, ASL, or AUL.

Therapy will follow the schema outlined in the study protocol.

Progress: No significant differences between the treatments were observed. In terms of complete response rates, the p-values are .30 (treatment comparison within good prognosis group) and .52 (treatment comparison within poor prognosis group). There was no significant difference in disease-free survival between ALinC 11 and ALinC 12.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7703	Status: Terminated

TITLE:

Radiation Therapy with BCNU, DTIC, or Procarbazine in Malignant Brain Gliomas, Phase III

Start Date:		Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Brain glioma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: Not applicable.

Technical Approach: Not applicable.

Progress: This study had been completed by the Pediatric Oncology Group prior to approval at BAMC.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7712	Status: Ongoing

TITLE:

Comparison of Treatment Regimens for the First CNS Relapse in Children with Acute Lymphocytic Leukemia - CNS #6

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To compare two therapies for CNS leukemia with respect to length of CNS remission and CNS toxicity.

Technical Approach: Patients less than 21 years of age at time of initial diagnosis with first CNS relapse who have not had more than one marrow relapse are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7721	Status: Completed

TITLE:

Evaluation of Induction, Remission Maintenance with and without Periodic Reinforcement, and CNS Prophylaxis in Acute Non-Lymphocytic Leukemia

Start Date: Nov 80		Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Non-lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: Evaluation of a remission-induction program in previously untreated acute non-lymphocytic leukemia (ANLL).

A chemotherapeutic regimen maintenance will be evaluated and the effects of periodic reinforcement with this regimen will also be evaluated.

The effects on development of CNS leukemia and the effects on prolongation of remission maintenance by the addition of CNS prophylaxis will be investigated.

Outcome by histologic subgroups will be evaluated in response to therapy.

Technical Approach: Patients under 21 years of age with a diagnosis of acute myelocytic leukemia, acute myelomonocytic leukemia, chronic granulocytic leukemia in blastic crises, erythroleukemia or other rare forms of myelocytic leukemia are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Duration of remission and survival by treatment group is as follows: VAP, Tr 1 - median duration 47 and 61 weeks, respectively; VAP Tr 2 - 54 and 58 weeks, respectively; TG & Ara-C - 15 and 40 weeks, respectively.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7799	Status: Ongoing

TITLE:
Rare Tumor Registry for Childhood Solid Tumor Malignancies

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Solid tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated at any single institution.

To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: This is a new study.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7812	Status: Ongoing

TITLE:

Anguidine in Central Nervous System Tumors

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Central nervous sytem tumors		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the anti-tumor activity of anguidine in the treatment of malignant brain tumors in children and adolescents relative to clinical response and survival.

Technical Approach: Patients with histologically confirmed primary CNS tumors as follows are eligible: astrocytoma, Grades III and IV; ependymoma, oligodendroglioma; medulloblastoma and patients under 21 years of age with clinical diagnosis of recurrent brain stem glioma following radiation therapy are elibible. Patients must not be eligible for protocols of higher priority or treatment of proven or likely higher efficacy.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 7818	Status: Ongoing

TITLE:

Rubidazone in Children with ALL and AML in Relapse

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the clinical efficacy and toxicity of rubidazone when used for the induction of remission in children with acute leukemia.

Technical Approach: Patients 21 years of age or under with acute leukemia in relapse, not eligible for protocols of higher priority, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 7829	Status: Ongoing

TITLE:

Comparison of Two Dose Regimens of Intrathecal Methotrexate for CNS Leukemia, Phase II

Start Date: 25 Sep 81	Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics	Associate Investigators:
Key Words: CNS leukemia	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To compare the toxicity, response rates and duration of response obtained by using a two dose regimen of intrathecal methotrexate.

Technical Approach: Patients under the age of 21 with CNS leukemia in relapse who are not known to be resistant to intrathecal methotrexate are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 7834	Status: Ongoing

TITLE:

Second Induction Maintenance in Acute Lymphocytic Leukemia, Phase III

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine in children in the first relapse of ALL in remission duration which can be achieved following an ingensive and aggressive induction regimen and maintenance.

Technical Approach: Patients under the age of 21 years in their first CNS and/or extramedullary and/or bone marrow relapse with acute lymphocytic leukemia are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 7837	Status: Ongoing

TITLE:

Evaluation of Systemic Therapy for Children with T Cell Acute Lymphatic Leukemia, Phase III

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphatic leukemia T-cell		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the effectiveness of a program of sequential systemic chemotherapy plus CNS treatment for children with untreated T-cell leukemia.

Technical Approach: Patients under the age of 21 with a diagnosis of T-cell leukemia as defined by SOWG 7865 including all patients who have 20% or greater E-rosetting leukemia cells are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 7843	Status: Ongoing

TITLE:

Evaluation of Rubidazone in the Treatment of Children with Solid Tumors, Phase II

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Solid tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the clinical efficacy of rubidazone in the treatment of malignant tumors in children with and without previous anthracycline therapy and to determine the toxicity of this drug in children with solid tumors.

Technical Approach: All patients under the age of 21 with a measurable tumor lesion, resistant to conventioanl chemotherapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7865	Status: Completed

TITLE:

Pilot ALinC 13C Acute Lymphoblastic Leukemia - Classification Portion

Start Date: Nov 80		Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphoblastic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: Subgroup classification of A.L.L. at time of diagnosis using a variety of laboratory methods. The present study is designed to:

1) familiarize each institution with the special subclassification laboratory procedures which will be required in ALinC 13 for patient registration;

2) collect data concerning laboratory subclassification results to determine in a preliminary fashion the degree of prognostic correlation of these results with already accepted clinical and laboratory prognostic factors (such as age, WBC, T-cell markers, etc.).

Technical Approach: Patients under 21 years of age with a diagnosis of acute lymphoblastic leukemia, acute undifferentiated leukemia, or acute stem cell leukemia are eligible.

Progress: No patients from BAMC were entered on this study. However, the study was completed by the Pediatric Oncology Group.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7895	Status: Ongoing

TITLE:

Multimodal Therapy for Management of Primary Non-Metastatic Ewing's Sarcoma of Pelvic and Sacral Bones.

Start Date: 25 Sep 81	Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics	Associate Investigators:
Key Words: Ewing's sarcoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the effectiveness of high dose intermittent chemotherapy to prevent local recurrence and/or metastases with surgical resection and a uniform radiation therapy regimen to control local disease.

Technical Approach: Patients with biopsy-proven localized Ewing's sarcoma with no prior chemotherapy and/or radiation therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 7906	Status: Terminated

TITLE:

Multidrug Adjuvant Chemotherapy in Non-Metastatic Osteosarcoma Comparison of CONPADRI I with COMPADRI V

Start Date:		Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Osteosarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: Not applicable.

Technical Approach: Not applicable.

Progress: This study was completed by the Pediatric Oncology Group prior to the final approval at BAMC.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7909	Status: Ongoing

TITLE:

Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of Localized Medulloblastoma and Ependymoma

Start Date: May 81	Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics	Associate Investigators:
Key Words: Medulloblastoma Ependymoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate the efficacy and toxicity of the MOPP adjuvant chemotherapy in the prevention of local recurrence of distant metastasis in children with localized medulloblastoma and ependymoma.

Technical Approach: Patients between 1 and 21 years (inclusive) with histologically proven medulloblastoma and ependymoma are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. The results of this study are too early to evaluate.

Detail Summary Sheet

Date: 2 Nov 81	Proj No: POG 7919	Status: Ongoing

TITLE:

Evaluation of m-AMSA in Children with Acute Leukemia and Non-Hodgkins in Relapse

Start Date: Nov 80		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Acute Leukemia Non-Hodgkin's lymphoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the clinical efficacy of m-AMSA, as indicated by the induction of partial or complete remission in pediatric patients with acute leukemia or non-Hodgkin's lymphoma in relapse.

To further assess the toxicity of m-AMSA in children.

Technical Approach: All patients with acute leukemia (lymphocytic and non-lymphocytic) or non-Hodgkin's lymphoma in relapse who are 18 years of age or under at the time of diagnosis, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: The results of this study are too early to evaluate.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 8000	Status: Ongoing

TITLE:
National Wilms' Tumor Study, III

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Wilms' tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To gain better understanding of Wilms' tumor by gathering detailed information regarding gross and histologic morphology.

To refine methods of treatment according to staging.

To test treatment hypotheses by randomized, prospective clinical trials according to stage and histologic grade of disease.

To gather information about family cancer in an attempt to identify children and familities at high risk.

To study the late consequences of successful treatment given for Wilms' tumor.

Technical Approach: Patients under the age of 15 with Wilms' tumor are eligible.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 8002	Status: Ongoing

TITLE:

Combination Chemotherapy with Adriamycin, Cis-Platinum, Vincristine, and Cytoxan in Children with Metastatic Neuroblastoma (Stage IV)

Start Date: 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics		Associate Investigators:
Key Words: Neuroblastoma, metastatic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To delineate the toxicity of the combination of cytoxan, vincristine, adriamycin and cis-platinum in children with metastatic neuroblastoma.

To do a preliminary analysis of the therapeutic efficacy prior to consideration of this four-drug combination as front-line therapy for children with Stage IV neuroblastoma.

Technical Approach: Children from 1 to 21 years of age with biopsy-proven metastatic neuroblastoma (Stage IV) who have not had prior exposure to cis-platinum are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Nov 81	Proj No: POG 8075	Status: Ongoing

TITLE:
Circulating Immune Complexes in Pediatric Malignancies

Start Date: 25 Sep 81	Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Pediatrics	Associate Investigators:
Key Words: Immune complex	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the incidence of elevated levels of circulating immune complexes at diagnosis in children with neuroblastoma, osteogenic sarcoma, ALL and AML.

To coreelate serial levels of circulating immune complexes with disease activity should significant quantities be initially detected.

Technical Approach: Newly diagnosed and staged patients under 21 years of age with neuroblastoma, osteogenic sarcoma, acute lymphocytic leukemia or acute myelogenous leukemia are eligible. Patients should not have had excisional surgery, chemotherapy or radiotherapy prior to initial serum sample.

Progress: This is a new study.

AUTHOR INDEX

ACKNOWLEDGEMENT

We regretted the departure of former BAMC Commander Brigadier General Andre J. Ognibene and wish him every success in his new endeavors. We are enthusiastic about the future with Brigadier General Tracy E. Strevey, Jr., the new Commanding General of BAMC.

In every organization there are those who never receive the recognition they deserve. Mrs. Bodie Bratten, the Editorial Assistant, and SFC Chuck Loyd, the NCOIC, have continually given that extra effort that has assured the success of the Department of Clinical Investigation for which I am most appreciative.

JAMES H. ANDERSON, JR., M.D.
Major, MC
Chief, Department of Clinical Investigation

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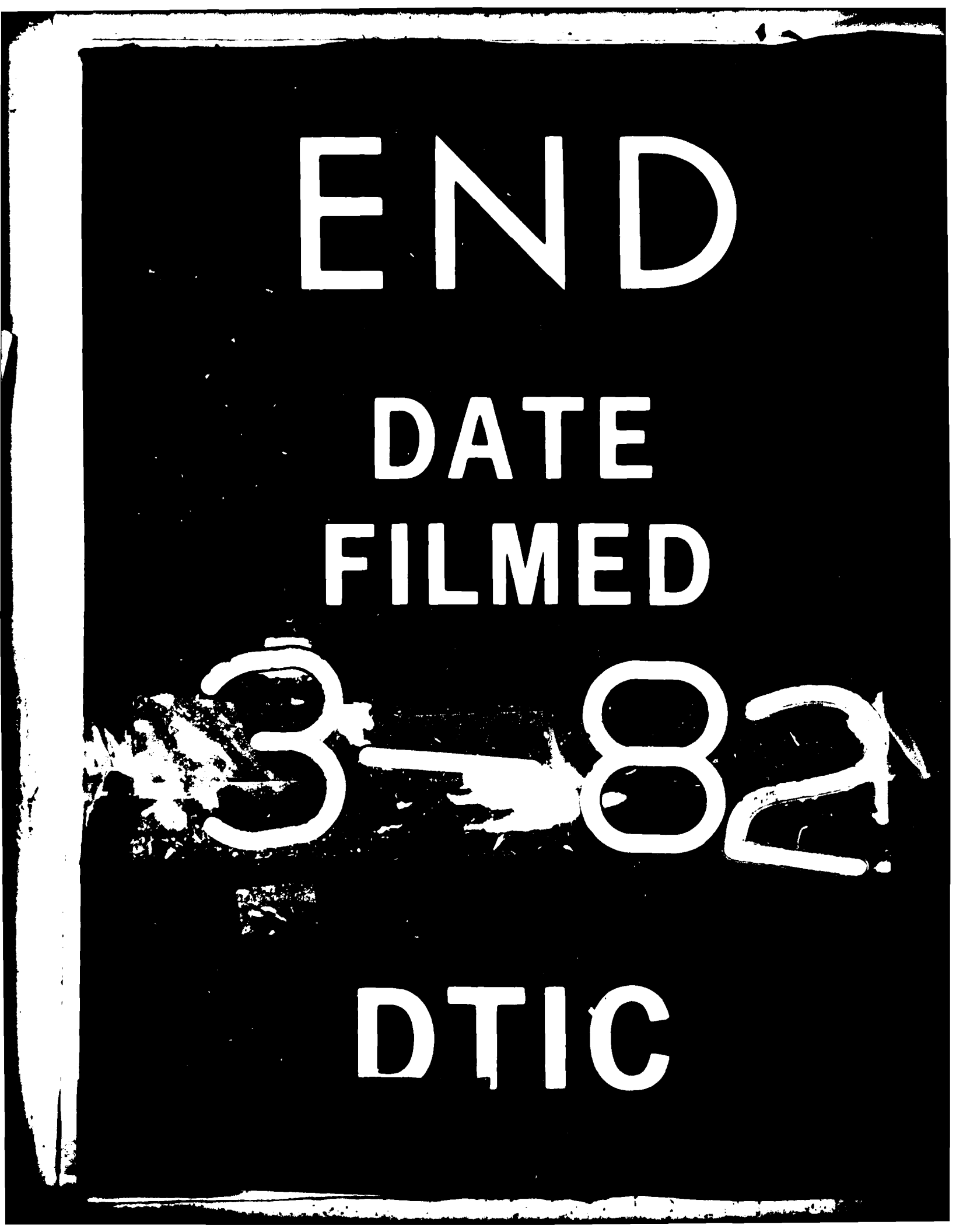
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